UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA; STATE OF CALIFORNIA; STATE OF DELAWARE; STATE OF FLORIDA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF LOUISIANA; COMMONWEALTH OF MASSACHUSETTS; STATE OF NEVADA; STATE OF TENNESSEE; STATE OF TEXAS; DISTRICT OF COLUMBIA; and STATE OF NEW YORK, *EX REL*. LAURIE SIMPSON, PLAINTIFFS/RELATOR, v. BAYER CORPORATION, BAYER AG, and BAYER HEALTHCARE PHARMACEUTICALS INC., DEFENDANTS.	Civil Action No.: 08-5758 (MJD/SRN) **SECOND AMENDED COMPLAINT**

TABLE OF CONTENTS

On behalf of the United States of America, the State of California, the State of Delaware, the State of Florida, the State of Hawaii, the State of Illinois, the State of Louisiana, the Commonwealth of Massachusetts, the State of Nevada, the State of Tennessee, the State of Texas, the District of Columbia, and the State of New York (collectively "the States and the District of Columbia"), Plaintiff and Relator Laurie Simpson ("Relator"), files this *qui tam* complaint against Defendants Bayer HealthCare Pharmaceuticals, Inc., Bayer Corporation and Bayer AG and alleges as follows:

INTRODUCTION

1. This is an action to recover treble damages and civil penalties on behalf of the United States of America in connection with the marketing and sale of the drug Baycol by Defendants Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer AG (collectively "Bayer") which conduct violated the False Claims Act, 31 U.S.C. § 3729, *et seq.* ("the FCA"). The false or fraudulent claims and statements at issue involve payments made by federal government-funded health insurance programs and by state funded programs including Medicare, the Federal Employees Health Benefits Program ("FEHBP"), TRICARE/CHAMPUS for prescription drugs, the Department of Defense and Medicaid.

2. Pursuant to the FCA, Relator seeks to recover, on behalf of the United States of America, damages and civil penalties arising from false or fraudulent claims that Defendants submitted or caused to be submitted to Federal Government funded health insurance programs.

I. SUMMARY OF THE ALLEGATIONS

3. The drug Baycol, also known as cerivastatin, is a drug that was used to treat and lower cholesterol. The drug was part of a group of drugs commonly known as "statins" which became popular in the past decade as a method of substantially lowering cholesterol in individuals with, or at risk of, heart disease. Between January 26, 1998, when it was launched, and August 8, 2001, when it was withdrawn from the market by Bayer, Baycol was one of the most important pharmaceutical products manufactured, marketed and sold by Bayer. U.S. sales of Baycol were approximately $290 million in 2000 and were projected to reach $591 million in 2001.

4. Baycol was removed from the market after multiple deaths and more than 1600 injuries were linked to the drug. In particular, it was found that patients who had been prescribed the drug were contracting a rare muscle disorder called rhabdomyolysis. Rhabdomyolysis can result in the need for dialysis, long hospitalization, disability and, in some cases, death. Adverse effects were even more frequent when Baycol was used in conjunction with gemfibrozil (another cholesterol reducer) or when patients were started on higher doses of Baycol. After the drug was removed from the market, over 10,000 patients or families of patients who had taken Baycol filed lawsuits against Bayer.

5. Among other government funded agencies, the Department of Defense had a contract with Bayer for Baycol, and paid millions of dollars to purchase the drug during the relevant time period.

6. Through the illegal kickbacks and misbranding detailed in this Complaint, Bayer caused false claims to be filed which would not have been paid had the full truth been known. The Relator is informed and believes that Bayer engaged in this deceptive

and misleading conduct for the purpose of increasing the overall market share of Baycol by inducing physicians to prescribe Baycol who otherwise would not have done so. As a result of its scheme, Bayer reaped millions of dollars in undeserved revenues and placed thousands of patients at unnecessary risk.

The Relator

7. The Relator is one of the most knowledgeable individuals about the marketing of Baycol at Bayer, having joined the marketing team for Baycol in April 27, 1998 as a Senior Market Research Analyst, just after the initial Baycol launch at the end of January 1998, first as a formal member of the marketing team (until January 2000) and then as a member of an extended marketing team when the market research function was centralized under the Strategic Analysis Department. She had the longest U.S. tenure of any marketing-related person on Baycol and was involved with the marketing of Baycol until the product was withdrawn from the market on August 8, 2001.

8. In this role, the Relator participated in the development and refinement of marketing messages, assessed product perceptions of Baycol and its competitors, evaluated communications to physicians and the public, conducted product pricing studies, participated in assessing sample requirements, participated in copy approval meetings, participated in Baycol product team meetings and participated on a Joint Marketing Team devoted to Baycol promotion.[1]

9. Relator routinely translated clinical trial information into potential marketing messages. For example, in 1999, she personally developed a list of more than

[1] The Joint Marketing Team was composed of SmithKline Beecham Corp. employees and Bayer employees who jointly marketed the product, pursuant to a Copromotion Agreement dated July 21, 1997. (In 2000, SmithKline Beecham ("SB") and Glaxo Wellcome merged to form GlaxoSmithKline ("GSK"). The new company began trading in January 2001.)

100 potential physician marketing messages based on actual and/or expected clinical trial results for a Messagemap® market research project she conducted, in conjunction with the vendor Migliara Kaplan, for the launch of Baycol 0.4 mg. She also did a similar project in April 2000 for the launch of Baycol 0.8 mg. (Messagemap® was a quantitative market research study used to assess how compelling individual messages were to physicians.) During promotional material market research and copy-approval meetings during her tenure on Baycol, Relator proposed alternative marketing messages based on her knowledge of Baycol clinical trials.

10. In Baycol Project Team meetings, she routinely and actively participated in discussions with other team members such as Mel Sorensen (Medical Affairs), Beth Crowley (Project Management), Carol Clark (Marketing), Pat Stenger (Scientific Affairs) and others, about the design and status of Baycol clinical trials and implications for various potential results. For example, in the Fall of 2000, Relator wrote an evaluation of the alternative actions that Bayer could take in the event of various results of an ongoing head to head trial of Baycol versus Zocor (simvastatin). The evaluation noted that if the results were not positive, then the results would not be used in marketing.

11. Starting in 1998, Relator conducted competitive intelligence activities and developed and maintained a clinical trial database of both completed and ongoing clinical trials for Baycol and for other statins. Her research was used as the basis for a published pamphlet on statin clinical trials entitled “STATS” that was distributed and used internationally by employees working on Baycol.

12. In 2001, she received copies of draft clinical trial protocols such as CHARGE, and provided recommendations regarding specific cardiologists for targeting as investigators based on their prescribing habits and specialty.

13. While Relator worked on Baycol, she provided input to clinical trial designs. Relator's early job description with regard to Baycol included such responsibilities as "input into clinical trial design."

14. Because of her close personal observations and knowledge about Baycol, Relator is uniquely positioned to detail Bayer's knowledge concerning the risks attendant with Baycol, when those risks became known and Bayer's steps to conceal those risks from the public and deceive the public about such risks.

15. From September 1998 through August 8, 2001, Bayer engaged in numerous improper and unlawful marketing strategies, including paying kickbacks, to increase the market share of its drug. Bayer also downplayed the risks of the drug for physicians who were prescribing the drug, thereby endangering the safety of patients who used the drug.

16. In particular, Bayer marketed Baycol with defective, inadequate and deceptive warnings with the intention of downplaying the risks that Baycol posed and consequently increasing its market share. Further, Bayer intentionally misrepresented, concealed or omitted facts and refrained from taking necessary steps to learn facts about the drug in connection with its communications with physicians, representatives of the Government, and the public.

17. If Government representatives who were responsible for purchasing Baycol from Bayer, or others who submitted claims to the Government for

reimbursement for Baycol, had known of the deceptive, misleading and other improper conduct, they would not have contracted for and/or purchased Baycol.

II. JURISDICTION AND VENUE

18. Pursuant to 28 U.S.C. § 1331, this District Court has original jurisdiction over the subject matter of this civil action since it arises under the laws of the United States, in particular the False Claims Act, 31 U.S.C. § 3729, *et seq*. Pursuant to 28 U.S.C. § 1367, this District Court has supplemental jurisdiction over the subject matter of the claims brought pursuant to the false claims acts of the States on the grounds that the claims are so related to the claims within this Court's original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

19. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because the False Claims Act authorizes nationwide service of process and the Defendants have sufficient minimum contacts with the United States of America.

20. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because acts complained of herein occurred in the State of New Jersey within this judicial district. This case was transferred to the District of Minnesota pursuant to order of Judicial Panel on Multidistrict Litigation in October of 2008.

21. Relator has complied with all procedural requirements required under the federal and various state False Claims Acts.

22. This Court has jurisdiction whether or not "public disclosures" under 31 U.S.C. § 3730c(4) have occurred because Relator is an "original source" under the Act. Relator is an "original source" under the Act because she has provided her information

voluntarily to the Government before filing this Complaint and has knowledge which is both direct and independent of any public disclosures to the extent they may exist.

III. THE PARTIES

23. Relator is a citizen and resident of the State of Connecticut. She brings this action for violations of the False Claims Act on behalf of herself and the United States of America pursuant to 31 U.S.C. § 3730(b)(1).

24. Relator is a former manager of market research for Bayer, until her employment was terminated effective on or about January 1, 2005.

25. Relator's knowledge of the facts set forth in this Complaint was personally acquired in the course of her employment with Bayer.

26. Bayer Pharmaceuticals Corporation, formerly located in West Haven, Connecticut, and its affiliates, subsidiaries, predecessors, successors, and assigns, were subsidiaries of Bayer Corporation, a $9.3 billion company with headquarters in Pittsburgh, Pennsylvania.

27. Bayer Corporation, and its affiliates, subsidiaries, predecessors, successors, and assigns, is a wholly owned subsidiary of Bayer A.G., a $30 billion international conglomerate headquartered in Leverkusen, Germany, with more than 140,000 employees working in approximately 150 countries around the globe.

28. Bayer HealthCare Pharmaceuticals, Inc., a subsidiary of Bayer A.G., and its affiliates, subsidiaries, predecessors, successors, and assigns, now operates four divisions of Bayer, including Bayer Schering Pharma A.G., and is the successor to Bayer Pharmaceuticals Corporation, which is involved in the business of research and development, manufacturing, marketing and selling prescription drugs throughout the

United States of America. Bayer manufacturers and markets many products and had reported sales in the United States of $10.1 billion in 2001 and $8.9 billion in 1999. The federal government, through its Medicaid and Medicare programs, as well as through other federal health insurance programs, is one of the principal purchasers of Bayer products.

IV. GENERAL ALLEGATIONS

A. Federal Government-Funded Health Insurance Programs

29. Medicare is a federal government funded health insurance program primarily benefiting the elderly that was created in 1965 when Title XVIII of the Social Security Act was adopted.

30. Medicaid is a federal and state assistance program to provide payment of medical expenses for low-income patients.

31. The Federal Employees Health Benefits Plan ("FEHBP") provides health insurance coverage for nearly 8.7 million federal employees, retirees and their dependents. FEHBP is a collection of individual health care plans, including the Blue Cross and Blue Shield Association, Government Employees Hospital Association and Rural Carrier Benefit Plan. FEHBP plans are managed by the Office of Personnel Management and collectively pay more than $2 billion annually in prescription drug benefits.

The TRICARE Federal Health Care Program

32. TRICARE is the uniformed services health care program for active duty service members and their families, retired service members and their families, members of the National Guard/Reserve and their families, survivors and other eligible

beneficiaries. The uniformed services include the Department of Defense (U.S. Army, U.S. Navy, U.S. Air Force, and U.S. Marine Corps), U.S. Coast Guard, the Commissioned Corps of the U.S. Public Health Service, and the Commissioned Corps of the National Oceanic and Atmospheric Administration. In 2002, the military spent approximately $4 billion on pharmacy benefits.

33. TRICARE's primary objective is to optimize delivery of health care services in the military's direct care system, which includes Military Treatment Facilities (MTFs).

34. TRICARE combines the health care resources of the uniformed services and supplements them with networks of civilian health care professionals, institutions, pharmacies, suppliers and other providers.

35. Under TRICARE, there are four major methods of obtaining a prescription: through a Military Treatment Facility ("MTF"), through the National Mail Order Pharmacy ("NMOP"), through the Retail Network, and through a non-networked pharmacy.

Military Pharmacies

36. Prescriptions may be filled (up to a 90-day supply for most medications) at an MTF pharmacy free of charge. Not all medications are available at MTF pharmacies. Each facility is required to make available the medications listed in the Basic Core Formulary ("BCF").

Tricare or National Mail Order Pharmacy (TMOP or NMOP)

37. Medications can be ordered online or through the mail, for up to a 90 day supply. There are co-pays for at least some classes of beneficiaries.

Medications Obtained through Civilian Pharmacy

38. If the pharmacy is part of the Tricare Pharmacy Network, the patient cost is the same as the Mail Order Pharmacy. There are higher co-pays for at least some classes of beneficiaries which depend on whether or not a Network or non-Networked pharmacy is used.

39. Starting in the Fall of 1999, statins were available to the DoD MTFs and the National Mail Order Pharmacy at a contracted rate. However, for beneficiary prescriptions obtained outside of these locations, that were obtained in retail networked and non-networked pharmacies, the government paid retail/civilian pricing (minus a co-pay) according to the DoD Pharmacoeconomic Center ("PEC").

40. In fiscal year 2000, DoD beneficiaries obtained 12 million retail pharmacy prescriptions, which cost TRICARE $455 million.

41. As of early 2001, there were an estimated 15,000 active duty DoD physicians and 152,000 TRICARE providers (belonging to HealthNet, Humana, Anthem, Sierra and Tri-West). Approximately 70% of the TRICARE physicians were being called on by Bayer field sales representatives (not including GlaxoSmithKline sales calls). 59% of prescriptions filled in MTFs for beneficiaries came from civilian providers.

B. The Relevant Statutes

The Anti-Kickback Statute

42. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), reflects Congress' concern that payoffs to those who can influence healthcare decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even

harmful to a vulnerable patient population. To protect the integrity of the program from these difficult to detect harms, Congress enacted a *per se* prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback gave rise to overutilization or poor quality of care. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions do not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b. Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

43. The Anti-Kickback Statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for federally-funded medical services, including services provided under the Medicare, Medicaid and (as of January 1, 1997) TRICARE programs. 42 U.S.C. § 1320a-7b(b).

44. The Anti-Kickback Statute makes it a crime to knowingly and willfully offer, pay, solicit or receive any remuneration to induce a person—

a. to refer an individual to a person for the furnishing of any item or service covered under a federal healthcare program; or

b. to purchase, lease, order, arrange for or recommend any good, facility, service, or item covered under a federal health care program.

45. The term "any remuneration" encompasses any kickback, bribe, or rebate, direct or indirect, overt or covert, in cash or in kind. 42 U.S.C. § 1320a-7b(b)(1).

The False Claims Act

46. Originally enacted in 1863, the False Claims Act was substantially amended in 1986 by the False Claims Amendments Act. The 1986 amendments enhanced the Government's ability to recover losses sustained as a result of fraud against the United States.

47. The False Claims Act provides that any person who knowingly submits or causes to be submitted to the Government a false or fraudulent claim for payment or approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government. The Act empowers private persons having information regarding a false or fraudulent claim against the Government to bring an action on behalf of the Government and to share in any recovery.

48. The False Claims Act is violated where a person submits or causes to be submitted claims based on deceptive information or causes one who receives or provides kickbacks or price discounts in connection with the purchase or sale of a reimbursable drug to seek reimbursement from a federal government-funded health insurance program for the drug. Specifically, the False Claims Act is violated by paying illegal kickbacks to healthcare providers who purchased and/or administered a reimbursable drug by causing them to falsely and expressly and/or impliedly to certify compliance with the Anti-Kickback Statute, and to seek reimbursement from Medicare, Medicaid, TRICARE, and other government programs for such false claims.

State False Claims Acts

49. Several states have False Claims Acts which closely track the Federal False Claims Act: California False Claims Act, Cal. Govt. Code § 12650, *et seq.*; the

Delaware False Claims and False Reporting Act, 6 Del. C. § 1201, *et seq.*; the Florida False Claims Act, Fla. Stat. Ann. § 68.081, *et seq.*; the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21, *et seq.*; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1-8; the Louisiana Medical Assistance Programs Integrity Law, 46 La. Rev. Stat. c. 3, sec. 437.1, *et seq.*; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 § 5A, *et seq.*; the Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.010, *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181, *et seq.*; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. § 36.001, *et seq.*; and the District of Columbia False Claims Act, D.C. Code Ann. § 2-308.03, *et seq.* (formerly § 1-1188.13, *et seq.*), and N.Y. Fin. Law § 187, et seq. (collectively the "States and the D.C. Acts").

Laws and Regulations Related to Misbranded Drugs

50. A drug is "misbranded" when its advertising or labeling is "false, lacking in fair balance or otherwise misleading." 21 C.F.R. § 202.1(e)(5)-(7). Regulations further provide that "[d]issemination of an advertisement not in compliance with this paragraph shall be deemed to be an act that causes the drug to be misbranded...." 21 C.F.R. § 202.1(j)(3).

51. According to 21 C.F.R. § 202.1(l)(1)-(2): (l)(1) Advertisements subject to section 502(n) of the act include advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems. (2) Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits,

literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, the "Physicians Desk Reference") for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling as defined in section 201(m) of the act.

52. Furthermore, according to 21 U.S.C. § 321(n), if an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

C. Defendant Bayer's Unlawful Marketing Schemes Relating to Baycol

The Baycol Drug

53. Baycol (cerivastatin sodium) was indicated for patients with high cholesterol. It is a HMG CoA Reductase Inhibitor (commonly known as a statin) used by physicians to control high cholesterol in patients with risk of heart conditions. Baycol's competitors were other anti-cholesterol drugs (statins) including Lipitor, Zocor, Pravachol, Lescol and Mevacor.

54. Bayer knew that, for Baycol to be a blockbuster drug and achieve sales targets, it had to market Baycol in an unfair and deceptive manner. The prescriptions resulting from the deceptive and unfair marketing would not have occurred had patients and physicians known the full truth about Baycol.

55. Bayer introduced Baycol in January 1998 in 0.2 milligram ("mg") and 0.3 mg doses. Bayer subsequently introduced a 0.4 mg dose in June 1999 and a 0.8 mg dose in August 2000. More than 2 million patients are estimated to have used Baycol from its introduction to the time Bayer removed it from the market. Of the patients who used Baycol, substantial percentages were Medicare or Medicaid beneficiaries.

Bayer's Contract with the Department of Defense

56. After the award, the Department of Defense had two statins on the formulary - Baycol and Zocor[2] (simvastatin). Bayer implemented "aggressive pull-through programs" to increase use in the Department of Defense. Significant costs were involved with switching patients to and eventually from Baycol.

57. Bayer management considered the Department of Defense contract an extremely important contract for the marketing and growth of Baycol.

58. Bayer's management intended to use the Department of Defense contract as a marketing tool to induce other clients to use Baycol. To entice the Department of Defense into entering into the contract, Bayer provided the Department of Defense with deep discounts on Baycol.

[2] Zocor was on the Department of Defense formulary for patients requiring higher LDL-C reductions.

The TRICARE Federal Health Care Program

59. Statins represented a large expense for the DoD and were identified as a prime opportunity for cost reduction. This was one of the first large-scale pharmaceutical bid contracts for the DoD, and was coordinated by the DoD PEC. The PEC provides administrative and technical support, including pharmacoeconomic analyses, for the DoD Pharmacy & Therapeutics Committee, which manages the DoD BCF and the Mail Order Pharmacy Formulary.

60. On October 23, 1998, the United States Defense Supply Center Philadelphia ("DSCP") of the Defense Logistics Agency of the DoD issued a solicitation (Request for Proposal) for HMG-CoA Reductase Inhibitors (statins) from manufacturers to supply statins to the DoD under a solicitation order which later became SP0200-99-1502.

61. The initial solicitation ("RFP") provided that the bids would be evaluated on two factors of equal importance: cost-efficacy and past performance.

62. A key premise underlying the cost-efficacy analysis was that statins were all similarly safe and had similar risk profiles.

63. The solicitation contemplated the award of one or two fixed-price national contracts for an 18-month base period with an option for an additional 2 one-year terms.

64. One contract was to be awarded under phase I for either atorvastatin (Lipitor) or simvastatin (Zocor); a second contract was to be awarded under phase II in the event that the addition of a second statin would yield a lower cost-efficacy ratio than would a single award. The solicitation provided for calculation of the cost-efficacy of any particular statin through a mathematical formula that considers both the drug's

annual cost per patient and the efficacy of the statin in lowering low-density lipoprotein cholesterol (LDL-C).

65. The DoD statin contract was an extremely lucrative and valuable contract for statin manufacturers, and all statin manufacturers (Novartis (Lescol), Parke Davis (Lipitor), Bristol Myers Squibb (Pravachol), Merck (Zocor) and Bayer (Baycol)) submitted bids.

66. The bidding process included several amendments to the original RFP, multiple bid protests, and bid iterations. Before the contract was awarded, the GAO was even involved.

67. On August 20, 1999, the United States contracting officer M.J. McKeown signed the award of the contract to Bayer Corporation, Pharmaceutical Division, for Baycol.

68. On September 22, 1999, the PEC announced the award to Bayer Corporation, Pharmaceutical Division for the supply of cerivastatin (Baycol) and thus closed the statin class on the BCF. As a result of the contract, the PEC mandated that Baycol be on all MTF Formularies and the DoD NMOP Formulary. All other non-contracted statins (atorvastatin, pravastatin, fluvastatin, lovastatin and any new statin approved by the FDA during the contract period) were not allowed on any MTF formulary.

69. In awarding the contract, the PEC selected Baycol and Zocor as "preferred statins." Baycol was designated as the "workhorse statin" and was expected to be used for the majority of patients requiring statin treatment and Zocor was to be used only for patients with more severely elevated high cholesterol.

70. The contract became effective on October 1, 1999, for an 18-month term, with an option for two additional years, extended one year at a time. The expiration date of the original contract was March 31, 2001.

71. The DoD mandated that patients who were currently taking a non-contracted statin should be converted to cerivastatin (Baycol) or simvastin (Zocor) no later than April 1, 2000.

72. The contract contemplated the purchase of Baycol for use by DoD in 0.2 mg, 0.3 mg and 0.4 mg tablets at the initial price of $.30 per tablet with an estimated base year value of $11,505,000. According to the contract, if the option were exercised after eighteen months, the per tablet price would increase to $.31 per tablet for an estimated annual dollar amount of $11,888,500. If the contract was extended a second time, the per tablet price increased to $.32 for an estimated annual dollar amount of $12,272,000.

73. The estimated total award of the Bayer contract (including the two extensions) was $35,665,500 for 38,350,000 tablets of Baycol per year.

74. The contract was administered by the Defense Supply Center Philadelphia—Medical at 700 Robbins Avenue, Philadelphia, PA 19111.

75. Earlier, in 1992, the DoD had established a formal pharmacy supply process for DoD pharmacies to order and receive pharmaceuticals directly from wholesalers, known as prime vendors. The prime vendor is a distributor of brand-specific pharmaceutical supplies who provides next-day delivery of those supplies, allowing MTFs to employ a "just-in-time" inventory method. Thus, purchasers (*e.g.* MTFs and National Mail Order Pharmacy) typically obtained Baycol from these distributors, and it would then be available for filling individual patient prescriptions.

Approximately 95% of drug purchases under the contract were expected to go through distributors on behalf of individual MTFs and the NMOP.

76. Under the Bayer contract, payment was made to Bayer by DFAS (Defense Finance and Accounting Service), a division of the Defense Logistics Agency-Columbus Center, DFAS-CO-SEM, P.O. Box 182317, Columbus, OH 43218-6248 for orders placed by DSCP - Medical. Orders by DSCP were expected to be approximately 5% of government purchases under the contract.

77. DSCP's Pharmaceutical Prime Vendor (PPV) and National Mail Order Distributors placed Baycol orders to Bayer for wholesale drug supply. These distributors then provided Baycol to MTFs and NMOP under the National Statin contract for just-in-time inventory to be used for filling beneficiaries' prescriptions. Thus, government funds were paid by the individual MTFS and NMOP for Baycol.

78. The place of performance of the contract was Bayer Corp. 400 Morgan Lane, West Haven, CT. 06516 and the mailing address for payment was Bayer Corp. PO Box 751384, Charlotte, NC 28275-1384.

79. The PEC Points of Contact for the Baycol Contract were LCDR Mark A. Richerson, MSC, USN, MAJ Don DeGroff, MS, USA and COL Dan Remund, MS, USA.

80. On January 11, 2001, the DSCP decided to exercise its option and modified the contract with Bayer to extend the period of performance from February 20, 2001, through February 19, 2002, for an estimated dollar value for the option year of $11,888,500. All other terms and conditions of the contract remained unchanged.

81. Throughout the contract, Bayer was very concerned that the DoD might cancel the Baycol contract or not extend the contract or that issues with Baycol might

jeopardize Bayer's chance at winning the VA/DoD Statin contract expected in 2001/2002.

82. Any omission of relevant clinical information or other off-label or misbranding activity would have affected the ability of the DoD to make an informed decision on whether to continue or extend the Baycol contract, as well as affected individual prescribing decisions.

83. DoD contract pricing applied only to prescriptions filled through MTFs and NMOP. The DoD paid retail pricing for beneficiaries' prescriptions filled in retail pharmacies (minus a copay), and these purchases fell outside the DoD contract. Furthermore, from at least August 8, 2000 onwards, at least some of the TRICARE Network Pharmacies only carried the two preferred DoD statins–Baycol and Zocor, thus facilitating additional prescriptions of Baycol.

84. On or about May 10, 2000, Bayer signed a contract with Humana TRICARE (Humana Military Healthcare Services) to provide Baycol to its beneficiaries consisting of dependents of active duty military personnel and military retirees and their dependents.

85. DSCP reimbursed Merck-Medco (who had the National Mail Order Pharmacy contract for the DoD) for purchasing and delivering Baycol to DoD beneficiaries.

Subsequent Introduction of Baycol 0.8 mg into Government Market

86. The Baycol 0.8 mg dose was used by the DoD even prior to FDA approval of the dose by prescribing 2 x 0.4 mg tablets. For example, Walter Reed hospital conducted a statin switch study that Bayer funded. Bayer approved the protocol which

called for pre-approval use of Baycol 0.8 mg for at least some of the patients. Bayer knew well before FDA approval of Baycol 0.8 mg that this dose had notable risks, particularly when starting on the dose.

87. Furthermore, Bayer medical personnel working with the investigator of this study were pleased when he decided to downplay adverse events when writing up the study, such as calling a case initially identified as rhabdomyolysis as myositis so as to appear that there was no serious adverse events in the study.

88. After the launch of Baycol in 0.8 mg in August 2000, the PEC evaluated this new dosage. The DoD was particularly interested in the potential for increased side effects and myalgias with the 0.8 mg dose and had been particularly interested in Baycol safety since the conversion of patients to Baycol in Fall 2000 had generated a number of cases of rhabdomyolysis.

89. The DoD was considering adding Baycol 0.8 mg to the National Statin Contract for Baycol.

90. A Bayer presentation to the PEC was held on August 23, 2000 to discuss Baycol. Prior to the meeting, LCDR Mark Richerson told Bayer he was particularly interested in the issue of myopathies with Baycol 0.8 mg. In response Carol Clark, Deputy Director on the Baycol marketing team contacted Tig Conger Vice President of CV Marketing to learn if the Baycol Rapid Response Team, a team created to specifically deal with Baycol safety issues, had discussed how to handle such inquiries.

91. Upon information and belief, there was no information provided to the DoD that Bayer had determined such a team was necessary, or that Bayer was aware of safety issues with Baycol.

92. It was subsequently learned that adding Baycol 0.8 mg to the National Statin Contract would have voided the contract due to a technicality. Furthermore, Bayer believed that Merck, Pfizer and BMS would protest Baycol 0.8 mg being added to the contract at $.50 per tablet (rather than $.30 per tablet), thus forcing a new bid. According to David Rose, Bayer manager for government affairs: "The last thing we want is a re-bid!!!!"

93. Instead, a special price of $.50 per tablet was given to the DSCP for Baycol 0.8 mg in October 2000 via a Distribution and Pricing Agreement ("DAPA").

94. On November 15, 2000, the DoD PEC Pharmacy and Therapeutics (P&T) Executive Council announced the approval of Baycol 0.8 mg and availability under DAPA pricing. The P&T Executive Council also announced that Baycol 0.8 mg provides "approximately the same percent reduction in LDL-C as simvastatin 40mg/day." Upon information and belief, and consistent with the Baycol marketing plans, Bayer neglected to tell DoD prescribers that head-to-head trials of Baycol versus simvastatin did not show equivalency in LDL-C reduction at these doses.

95. The DAPA was later terminated by Bayer in favor of all Federal pricing going to Federal Supply Schedule (FSS) pricing, and the special price was cancelled by Bayer which increased the price of the 0.8 mg dose to the DoD.

96. On February 14, 2001, Bayer and the DoD entered into a Blanket Purchase Agreement ("BPA"), whereby Bayer supplied bottles of Baycol 0.8 mg tablets at $15.00 for 30 tablets and $45.00 for 90 tablets. Thereby Baycol 0.8 mg tables were added to the DoD Pharmaceutical Prime Vendor ("PPV") Database so all MTF's had access to the 0.8 mg dose of Baycol at a discounted price.

97. The BPA commenced on February 15, 2001, and was scheduled to end on December 31, 2002. The Point of Contact for the BPA was LCDR Fred Beal, Chief, Pharmaceuticals Products Group National Contracts and DAPA Section.

98. The BPA was signed by Joann Fiengo on behalf of Bayer and M.J. McKeown on behalf of the DoD.

99. The BPA could not be made retroactive, thus there was a period of time after the October 2000 DAPA was cancelled by Bayer when DoD (or at least some MTFs) were unknowingly paying a premium for the Baycol 0.8 mg tablets (*i.e.* the price listed on the Federal Supply Schedule).

100. On February 20, 2001, Capt. Hirsh at the Naval Medical Center in San Diego requested information on 0.8 mg and dose related side effects in a request noted by Bayer as ”formulary issues.” In response, Bayer sent a standard Baycol 0.8 mg efficacy letter with references and prescribing information, which was unlikely to have provided the information sought by Capt. Hirsh and omitted relevant safety information known to Bayer.

101. On May 3, 2001, McKeown notified Bayer that it was cancelling the BPA for Baycol 0.8 mg tablets effective on June 3, 2001.

102. This cancellation was due to a contract challenge by Merck. At the time, Merck was communicating to physicians about undisclosed safety concerns related to Baycol.

103. On July 30, 2001, David Rose, Manager, Federal Government DoD for Bayer, alerted colleagues at Bayer to questions asked by the DoD PEC on a July 27, 2001 conference call with COL Dan Remund (PEC Director), Dave Bretzke (DoD Statin

Contract Point of Contact), CAPT Joe Torkildson (PEC Associate Director), COL Don DeGroff (Army Pharmaceutical Consultant), CDR Ted Briske (Navy Pharmacy Consultant) and LTC Ed Zastawny (Air Force Pharmacy Consultant) held to discuss concerns related to Bayer's recently issued "Dear Prescriber" letter. The key questions posed included: "What was the basis of the Dear Prescriber letter about 0.8 mg initial dosing?" "Is there any increased adverse effects of 0.8 mg (vs. 0.4 mg) in absence of combination therapy (niacin, gemfibrozil, or anything else)? If so - what are they and what is the magnitude of the change?" Bayer knew there were safety issues with the Baycol 0.8 mg dose, particularly when using it for a starting dose, since at least December 1999. These key questions reveal that Bayer had not communicated this knowledge to the DoD, even up to a week before Baycol was withdrawn from the market.

104. On August 14, 2001, the PEC reported that as of the complete withdrawal of Baycol from the market, over 115,000 Baycol patients were being treated in the military healthcare system.

Bayer Downplays Safety Concerns and Oversells Efficacy

105. On November 9, 1999, Casimir Zygmunt ("Zygmunt") RPh, Clinical Specialist from Bayer Clinical Communications responded to inquires regarding the safety of Baycol to LCDR Richerson. The inquiries by LCDR Richerson were prompted by cases of rhabdomyolysis associated with the use of Baycol by patients treated at MTFs.

106. After two letters to LCDR Richerson from Bayer Clinical Communications regarding Baycol safety, on November 16, 1999, DoD requested a more

detailed analysis of the data, including analysis of the relative incidence of the occurrence of rhabdomyolysis associated with Baycol as compared with other statins.

107. On November 10, 1999, Zygmunt reported to a DoD contact that there is "[n]o evidence to suggest that Baycol causes more rhabdo then (sic) others-it is a class effect." This is a false statement because Bayer did possess evidence at the time ***suggesting*** that Baycol did cause more rhabdomyolysis than other statins.

108. By November 10, 1999, the date of the government's inquiry, there had been two adverse event analyses demonstrating a higher adverse event ***reporting rate*** for rhabdomyolysis for Baycol versus other statins, and this was prior to any adverse publicity that may have been generated after the contraindication.

109. On November 24, 1999, Bayer held a telephone conference regarding the government's safety concerns with Baycol including comparisons with other statins of the incidence of rhabdomyolysis with DoD participants including the following military officials: Col. Dan Remund, Director of the DoD PEC in San Antonio, Texas, Commander Mark Brouker, Assistant Director of the PEC and Navy Pharmacy Consultant, LCDR Mark Richerson, the Navy Pharmacy Consultant who is the Point of Contact for the DoD Statin Award Implementation Plan and LTC Rick Downs, MD, a Leading Investigator/Thought Leader in Military Cardiovascular Medicine, Lead Investigator in the Air Force Texas Coronary Atherosclerosis Preventions Study, and Internal Medicine Residency Program Director at Wilford Hall Air Force Medical Center.

110. On December 3, 1999, in a letter to LCDR Mark Richerson at the DoD PEC (one of the lead DoD people for the statin contract), discussing the proposed contraindication with gemfibrozil and rhabdomyolysis, Mel Sorensen, Director of

Medical Research at Bayer reminds the DoD that the reason the DoD decided to include Baycol on the formulary was for its "proven efficacy and tolerability."

111. This letter also notes that "importantly, none of these cases have resulted in death." Shortly thereafter, Bayer had two reports of death associated with Baycol and rhabdomyolysis. Upon information and belief, Bayer did not convey "important" information back to the PEC that Baycol was indeed capable of and was in fact causing patient deaths.

112. The letter also poses the following question: "Is the frequency or severity of rhabdomyolysis associated with Baycol dependent upon the dose of either agent?" Bayer falsely states that "…there are insufficient data upon which to base a dose-response relationship," however, Bayer was aware at the time that there was in fact a dose-response relationship with Baycol's adverse side-effects. In fact, at the international APZ (safety) meeting on December 14, 1999 (less than two weeks after the letter to the PEC), in the minutes document Thomas Schubert, the head of Global Strategic Marketing for Baycol, stated that .8 mg should probably not be used for women at all, and in men, .8 mg should be used only after titration.

113. On December 15, 1999, Richard K. Goodstein, MD, Vice President, Scientific Relations for Bayer, issued a widely distributed letter addressed to "Dear Health Care Professional" stating that "While no cases of rhabdomyolysis were reported during the extensive clinical trials of Baycol (cerivastatin sodium tablets) there have been a number of cases reported during the post-marketing period, the majority of which involved patients taking concomitant Baycol and gemfibrozil." This statement was false

as Bayer did have at least one adverse event report of rhabdomyolysis in a clinical trial patient who used Baycol in combination with gemfibrozil.

114. Bayer also discounted cases of rhabdomyolysis in monotherapy. Instead, Bayer focused attention on rhabdomyolysis as a result of co-prescribing with gemfibrozil, and ignored the data and internal concerns about the increased rhabdomyolysis adverse event reports versus other statins in monotherapy.

115. Bayer internal data presented at a key safety meeting held on December 14, 1999, noted that there have been 72 reported cases of rhabdomyolysis in the US. Bayer, however, despite this information subsequently sent a letter dated December 20, 1999, to the FDA that reported only 47 cases of rhabdomyolysis.

116. On January 4, 2000, David Rose, a Bayer employee, reported that LCDR Mark Richerson asked for the current number of rhabdomyolysis in the DoD. Rose also reported on that date, that "[i]n a survey of 52 MTF's (thru Dec. '99) there are currently 18,000 Baycol patients within these [MTF] facilities." Richerson had also asked for the number of rhabdomyolysis cases from Bayer Clinical Communications, who told Richerson that the complete data resides with Bayer Drug Safety Assurance and that he would be provided the information. As Rose reported, Richerson was giving a presentation on January 12, 2000 to all of the DoD Chiefs of Pharmacy at a meeting in San Antonio, Tx; [and] . . . he'd like to put the # of Rhabdo cases in perspective with the current Baycol utilization #'s." Rose reported that Richerson would "very much like to put the Rhabdo issue to rest!!!!!"

117. On January 13, 2000, David Rose reported to four colleagues at Bayer that "based on communications with the Tricare Regions thru 1/7/00 there are a total of 20

Baycol/Rhabdo cases with the D.o.D." Rose further reported to his Bayer colleagues that "[t]he P.E.C. has queried 52 MTFs and found that within those facilities there are currently 18,000 patients on Baycol (the D.o.D. total would be higher) when factoring in the 20 Rhabdo cases the % is .0011; not a very large #." In response to Rose's e-mail report another Bayer manager, Bob Harrison stated "We will continue to cc Brian Russell when Clinical Communications forwards the details to Drug Safety Assurance of any case of rhabdomyolysis associated with Baycol received by Clinical Communications. Whenever possible, we will ask the identity of the patient's managed care plan or whether the patient is part of the DoD system." Harrison reported that "Rose maintained a spreadsheet of incidence of rhabdomyolysis among DoD patients and that information would be maintained by Bayer employee Roger Celesk, of Bayer Drug Safety Assurance."

118. On January 14, 2000, David Rose sent a report to Bayer "Government Account Managers" as follows:

> "Today I spoke at length with LCDR Mark Richerson about the D.o.D. Statin Bid and his presentation to the D.o.D Chiefs of Pharmacy at the P.E.C. conference this week in San Antonio. Below are some key points:
>
> Baycol patients now make up 30% of the D.o.D. Statin Patients thru 1/10/00. **(this is a 9% increase in 10 days!!!!!)**
>
> LCDR Richerson's "Rhabdo" presentation on 1/12/000 at the PEC Conference was very well received by the Chiefs of Pharmacy and he feels that the point has been made and positively received that the incidence of Rhabdo with Baycol patients is less than .0011 in the D.o.D. and that to his and the audience's

knowledge. **No other statin company has come out and actively promoted their product for combination use with Lopid** (Rhabdo is mentioned in all Statin P.I.s, [Product Inserts] therefore the audience views this as a Class problem and not just one for Baycol). He feels that the Baycol P.I change won't be a major setback for Baycol in the D.o.D.

119. Despite the contraindication of use Baycol in combination therapy, military pharmacists reported that they considered the use of Baycol as well as all other statins with fibrates to be a relative contraindication not an absolute contraindication. Maj. Larry Gudgel, PharmD at Wright Patterson AFB reported to Bayer employee Cyndi Creech that he had a total of about 20 patients, primarily diabetics, who were being treated with combination therapy, 3 of which were on Baycol. Maj Gudgel reported that new information in no way would alter their efforts to convert patients to Baycol according to the PEC guidelines.

120. On January 14, 2000, three Bayer employees who handle government contracts reported to David Rose that at Walter Reed Army Medical Center and Bethesda Naval Medical Center, "[t]here appears to be little concern for the rhabdo issue. Everyone knows that contraindication is there, and that rhabdo is a potential not only with Baycol, but all the statins, so it seems to be a non-issue at this point." Bayer's government liaisons reported that program to switch military patients to Baycol was "getting in full swing" and the expected target of switching 70% of statin patients to Baycol was probable.

Bayer Was Well Aware Yet Concealed Its Safety Concerns with Baycol

121. The existence of reports of rhabdomyolysis, particularly in conjunction with gemfibrozil, was known by Bayer from early 1998. Bayer has stated that adverse event reports of Baycol causing rhabdomyolysis both in monotherapy and in combination with gemfibrozil were not unexpected and not of concern. This is inaccurate. Relator participated in Baycol Project Team meetings and multiple other discussions where this concern was discussed on multiple occasions.

122. Upon information and belief, these increasing reports of rhabdomyolysis were downplayed to the FDA as Bayer categorized them as "expected" despite the magnitude of the number.

123. Bayer has always stated that the warnings for Baycol were adequate to describe the potential side effects. However, Bayer made material omissions and false statements by stating or implying that the risk of such side effects was similar to other statins. While the statement that "all statins have warnings" is true, the result was to leave the recipient with the false impression that the risk was similar to other treatment options. When Relator expressed concern that prescribers would then discount the contraindication because they had safely used other statins in combination (as expressed in a memo she wrote to Tig Conger in August 2000), she was again refocused by management on the fact that the statement was technically true. It did not seem to bother Bayer decision makers that the statement was misleading and threatened patient stafety. If the DoD and other prescribers had known the truth (which DoD attempted to discover on multiple occasions), then it is unlikely the DoD would have entered into the contract with Bayer or would have extended the contract. In any case, the DoD and prescribers

for DoD beneficiaries were not fully informed, thus influencing their professional judgment.

124. By at least June 2000, internal Bayer documents state that Baycol does have more CK elevations than any other statin, and that the rate of adverse reaction events is correlated to the dose.

Fraud in the Pacificare Studies

125. Bayer was aware from at least April 1998 of a signal for an increased rate of adverse events with Baycol when three cases of rhabdomyolysis were identified just after Baycol's launch. Comparative analyses of adverse event reports for various statins were first conducted in April 1999 and further comparative research was recommended at the time.

126. Eighteen months after additional safety studies were first proposed, in the Fall of 2000 with increasing adverse events and increasing attention to safety matters, Bayer could no longer postpone conducting comparative studies of Baycol safety.

127. In exchange for putting Baycol 0.8 mg on its formulary, Bayer worked out an arrangement for Pacificare to conduct analyses of its medical and pharmacy claims databases to look at Baycol safety as compared to competitive statins.

128. Bayer relied on studies conducted by Pacificare in 2000 (preliminary analysis) and 2001 (formal studies) to purportedly document the safety of Baycol as compared to other statins. This information was used in labeling as defined by the FDA, which includes sales representative training bulletins, verbal communications, presentations to prescribers (including civilian physicians who treated government

beneficiaries), and representations to the FDA, DoD and other government contracting agencies.

129. The Pacificare studies, however, were fraudulent and misrepresented the safety of Baycol. Bayer management knew that the methodology applied in the Pacificare studies was biased to favor Baycol's safety.

130. In mid-1999, after Bayer and Pacificare signed a contract placing Baycol on Pacificare's formulary, Pacificare removed Lescol (fluvastatin) from its formulary and replaced it with Baycol as one of two statins.

131. For the studies, the timeframe chosen as the index period was from July 1999 through December 1999. During that period, Pacificare was switching patients who were receiving statin therapy to Baycol.

132. During the index period timeframe, Bayer distributed free 30-day samples to Pacificare physicians for use by individual patients with the intention that physicians would give patients a 30-day supply of Baycol along with a Baycol prescription in an effort to increase usage of Baycol.

133. Tig Conger, the Vice President of Bayer Cardiovascular and Metabolic Marketing and one of the three key people who reviewed and oversaw the Pacificare studies, was aware that 30-day samples of Baycol were being distributed and used by patients in this timeframe.

134. Conger was aware that Pacificare physicians were specifically targeted for Baycol promotion (including 30-day samples) because of their high potential for writing large numbers of Baycol prescriptions as a result of the closed formulary.

135. In addition to discussions on sampling by dose and by packaging size, including the 30-day supply samples, between Relator and Conger, the fact that Conger possessed this information prior to the widespread distribution of the Pacificare study results was confirmed when, in April 2001, at Conger's request, Relator provided Conger a report on Baycol sampling by dose which clearly showed distribution of 30-day samples to physicians during and around the index time frame.

136. Bayer and Conger were also aware that the median duration of time from initiation of Baycol therapy to the onset of symptoms of rhabdomyolysis was 31 days.

a. By using the selected index period timeframe and the issuance of free 30-day samples of Baycol during the index timeframe, the Pacificare study results are skewed to favor the safety of Baycol. Under the study methodology, patients who received samples of Baycol (but did not fill their Baycol prescription immediately) and suffered an adverse reaction were improperly excluded from any association with Baycol and the adverse reaction was ascribed to the predecessor statin that was replaced by the Baycol sample. This methodology thus decreased the reported incidence of adverse reactions from Baycol and increased the adverse reaction attributable to another statin prescribed prior to the patient receiving a Baycol sample.

b. One of the widely communicated conclusions from the Pacificare studies was that Lescol had a substantially higher rate of rhabdomyolysis in monotherapy as compared to Baycol. This finding was inconsistent with the available clinical data for Lescol; however, it is entirely consistent with misattributing adverse events caused by Baycol sampling to the predecessor statin. (For example, an FDA analysis of serious rhabdomyolysis events done in mid-2000 found 26 reported cases of serious

rhabdomyolysis associated with Baycol monotherapy, while there were only 2 cases reported for Lescol, and Lescol had been on the market since 1995 and had a larger market share of prescriptions.) Given that Bayer was monitoring FDA Medwatch data for all statins, Bayer either recognized or should have recognized that there was a bias in the Pacificare methodology.

137. In mid to late 2000 and 2001, Conger rejected suggestions to use other databases to help research comparative safety and/or validate the Pacificare "findings."

138. Bayer's knowledge that the Pacificare studies' methodology were inherently biased, while Bayer publicly maintained that they demonstrated Baycol had similar safety to other statins, constituted fraud.

Bayer's Deceptive Marketing of Baycol

139. Because of the tremendous success of other statins in the marketplace, Bayer was interested in offering its own statin drug to compete in the market for anti-cholesterol drugs.

From the Start, a Comparable Safety Profile to Other Statins was Considered a Critical Success Factor

140. At the time that Baycol was launched, statins were considered relatively safe drugs. As Dr. Mel Sorensen, Bayer Medical Director on Baycol put it, "[An] Excellent Safety Profile is Expected."

141. Relator was aware that the common internal sentiment within Bayer was that it would be commercially damaging for Baycol to be perceived as having a worse side effect profile than other statins.

142. Senior Bayer management was on notice that if Baycol evidenced even one (significant) drug interaction, it could substantially impact the entire marketing

campaign and sales of the drug. In 1997, when Bayer was preparing to launch Baycol, Strategic Marketing Corporation ("SMC Europe Inc.") conducted an international market research study regarding Baycol and the potential impact of drug interactions in marketing a cholesterol-reducing drug. In the report dated October 13, 1997 (Cerivastatin: Product, Product Concept and Drug Interaction Profile), it is noted that as few as "one DI [drug interaction] only kills the drug: 'Asking for Liabilities.'" The report went on to note that drug interactions would be a "Competitive Vulnerability ('Suicide if it Happens')."

143. From the beginning of the marketing campaign for Baycol, Bayer engaged in marketing with the intent to communicate to physicians and purchasers that Baycol was superior to other competing anti-cholesterol drugs because it did not have any significant drug interactions and had a superior safety profile. While the message was originally based on the statement that Baycol did not interact with warfarin[3] and digoxin, the actual message Bayer conveyed to the public was that Baycol had no significant drug-to-drug interactions.

144. The fact that Baycol had a dual metabolic pathway was also used to support the message that Baycol was a safer product than other statins. Although Bayer knew that people were dying as a result of taking Baycol in combination with gemfibrozil, Bayer included the message of low risk of drug-to-drug interactions as a result of the dual route of metabolism in marketing material and messages almost up to the time of Baycol's withdrawal.

[3] There were subsequent questions regarding the accuracy of the lack of interaction with warfarin claim.

Senior Management Wanted to Aggressively Maximize Baycol Profits

145. On September 30, 1998, Relator was present at a key Baycol Brand Review Meeting where the then current CEO of Bayer, Dr. David Ebsworth, expressed significant disappointment at Baycol sales-to-date and directed that Baycol should be marketed more aggressively. The official meeting minutes reflect Dr. Ebsworth's sentiments: "Other companies have developed an attitude of pushing marketing materials aggressively, following the philosophy: 'we do no[t] know where the legal boundary is until we hit it.' One may not value this – but since it is the rule in the market, we as a company have to follow it. The area is grayer than we treat it, e.g. we can pick the better study for the detail aid."

146. Dr. Ebsworth also directed that Baycol should be marketed as comparable in efficacy to Lipitor, a strategy that the current clinical data did not support.[4]

147. In addition, documents that Relator believed to be misleading were circulated at that meeting, including documents showing deceptive responder rates.[5] In fact, certain key graphs did not provide complete data for all patients. A decision had been made to exclude those patients that did not respond well to the drug.

148. Relator expressed numerous concerns to product management about what she believed to be the unethical behavior of senior management in connection with misleading statements made at the meeting and the manner in which the meeting was

[4] At the time, no available clinical data showed that Baycol 0.3 mg was equivalent or more efficacious than the lowest dose of Lipitor (10 mg). According to the respective Prescribing Information, Baycol 0.3 mg produced 28% LDL-C lowering, while Lipitor 10 mg provided 39% LDL-C lowering.

[5] Responder rates - Not all patients will experience the same response to a drug, in this case Baycol. The responder rates provided a graphic distribution of the cholesterol-lowering achieved by patients.

conducted. (These meetings were frequently designed to appear that decisions were based on group consensus, when in reality, it was clear that senior management manipulated discussions to achieve certain objectives and outcomes decided before the meetings.)

149. Although others told Relator they felt similarly, it was made clear by Bayer's management that it was politically unwise to voice concerns about Bayer's practices. Immediately after this meeting Dr. Ebsworth authorized and spearheaded the distribution of the deceptive responder rate graphs to Baycol sales representatives for use in detailing, thus authorizing the use of "homemade bread" or non-approved sales material.

150. According to Bayer's internal HealthCare Compliance Code of Conduct guidelines, which were signed by Dr. Ebsworth, the use of "homemade bread" was a strictly prohibited activity. The fact that Dr. Ebsworth was advocating and enabling a prohibited activity made it clear to the Relator that Bayer was not fully concerned with complying with legal requirements and acting ethically.

151. Bayer's intention to aggressively market Baycol and push the legal boundaries as depicted by its CEO's statements, was reflected in numerous actions taken during this time period. For example, Relator is informed and believes that a number of marketing individuals were subject to adverse employment actions (including internal transfers) related to Baycol, which were motivated, in part, by Bayer's desire to employ only the most aggressive marketing personnel for Baycol and Bayer's unrealistic sales expectations. These individuals included Carlton O'Neil (1998), Jim Patchen (1998), William Geary (1999), Julie Goodwin (1999), and Mary Bauman (1999), among others.

Aggressive Marketing Resulted in FDA Warning Letter from DDMAC[6]

152. In early 1999, prior to Bayer's launch of the 0.4 mg dose, a sales aid was under development that contained several graphs ("The Science for Success" and "Pure Enzyme Inhibition") that were considered very risky and likely subject to FDA warnings.

153. In addition, the product management team attempted to minimize the typeface and visibility of the safety information for Baycol promotional materials so as not to call attention to it. This effort to minimize important safety information was consistently followed with all Baycol sales aids that were distributed to sales representatives.

154. Senior Management discussed the risks associated with using material that likely violated FDA regulations and concluded that it would be acceptable to use because by the time the FDA reviewed the questionable material, another Baycol sales aid would be out, and therefore the impact of any FDA warning letter would be negligible.

155. In addition, Bayer's Product Management Team concluded that it was too risky to develop a "Slim Jim"[7] form of the sales aid because physicians would retain them, thereby increasing the risk of FDA attention and creating written documentation of its deceptive practices. Based on pressure from the sales representatives, Product Management eventually agreed to provide the Slim Jims.

156. On or about October 25, 1999, the FDA sent a warning letter regarding these promotional pieces.

---

[6] Division of Drug Marketing, Advertising and Communications

[7] A Slim-Jim is a pamphlet form of a sales-aid designed to be left for the healthcare provider.

Bayer Learned That There Were More Reported Adverse Events for Baycol Than for Other Statins

157. In early 1999, Relator participated in a Baycol Project Team meeting where it was noted that there had been increasing cases of rhabdomyolysis reported for Baycol. As a result, Relator agreed to obtain adverse event information from the FDA though a Freedom of Information Act ("FOIA") request. Although the Project Team only initially requested information on competitive statins, Relator proactively obtained information on Baycol adverse events as well. At the time of the request, Baycol 0.3 mg was the highest dose on the market.

158. Once the adverse event information was obtained, Relator drafted a summary and circulated it to product management. This summary included a paragraph stating that there was very likely a material difference in adverse event rates between Baycol and other statins, and that further investigation should be pursued. When Bayer management reviewed the report, Relator was directed to remove this conclusion from the report "in case of litigation."

159. That conclusion was subsequently removed prior to additional distribution. While Relator did not believe that an accurate assessment of the adverse event *rates* could be made from the FDA Medwatch FOIA data, it seemed clear that the adverse event rate for Baycol was not the same as that for other statins. In addition, Relator found that there appeared to be not only a concern when Baycol was used in combination with gemfibrozil, there also appeared to be an elevated risk when Baycol was used as monotherapy as well.

160. The FOIA summary was given to Bayer's drug safety group with the expectation that they would conduct the necessary follow-up and/or statistical analyses to

formally conclude that the adverse event rate for Baycol was not the same as for other statins.

161. Relator also communicated secondary reports such as journal articles that concluded that adverse events reported into adverse event reporting systems such as the FDA MedWatch system could be expected to significantly underreport the actual incidence of adverse events.

Bayer Used Ghostwriters to Allay Safety Concerns

162. On or about April 5, 1999, during a Baycol Project Team Meeting, one of the attendees raised concerns about a recently released article in the *American Journal of Cardiology* concerning a case of rhabdomyolysis involving Baycol and gemfibrozil, and the potential for the article to negatively impact Baycol sales.[8] The team wanted to respond to the article in order to allay concerns regarding the safety of Baycol and minimize any impact.

163. Bayer solicited opinion leaders ("OL") to sign a ghost-written internally drafted and Bayer-approved response to the article. Under the guise of a scientific correction, the objective and intent of the response was to allay concerns regarding the risk of rhabdomyolysis when using Baycol, concerns that Bayer knew were valid given the amount of information that Bayer knew at the time. This response was subsequently published in the *American Journal of Cardiology*.[9]

---

[8] Rhabdomyolysis and renal failure associated with cerivastatin- gemfibrozil combination therapy, by Pogsdon, Kindred, and Carper. *AJC*. 83(7) 1999, 1146.

[9] Guyton JR, Dujovne CA, Illingworth DR: Dual hepatic metabolism of cerivastatin-clarifications. Am J Cardiol 1999, 84:497

Bayer Restructured Safety Organization for Additional Control

164. In August 1999 (a few months after the circulation of the first Baycol FOIA adverse event analysis report), there was a corporate e-mail from the Medical Directors Management Meeting[10] ("Management Meeting") "regarding the start of Project Redirection Medical." The Bayer Management Committee approved the "Redirection Medical" project.

165. The Management Meeting e-mail announced the "reengineering" of Bayer's Drug Safety activities "in such a way that a global process with a single Bayer opinion is implemented." The country drug safety units were to report directly to the global unit and the global unit was to assume responsibility for "issue management." The new organization was entitled "Global Drug Safety." Relator believes that these actions, taken after management's awareness of the Baycol adverse event issue, led to delays in communicating important drug safety information to United States physicians because the Bayer Management Committee now required a single global Bayer opinion on safety matters and now exercised close control over the output.

Management Control Over Safety Matters Demonstrated

166. E-mails and discussions with Bayer personnel suggest that a number of employees (including some members of senior management) were uncomfortable with the handling of Baycol safety issues. Dissension was not tolerated and at least one senior management official who expressed concerns was effectively demoted after the withdrawal of Baycol.

[10] The Medical Directors Management Meeting included Frank Armstrong, Paul McCarthy (Medical Director for the United States), Gisela Brill, Ronald Grobe-Einsler, and Thomas Weihrauch. Larry Posner and others were listed as part of the extended Management Meeting.

Bayer Issued Deceptive Press Release

167. On September 30 1999, Bayer AG issued a press release entitled "Should Cerivastatin be the Drug of Choice in Treating Diabetic Hyperlipidemia," which deceptively suggested that Baycol was an ideal statin for use in combination with fibrates even though, at the time, Bayer possessed substantial data suggesting use with gemfibrozil (the most frequently prescribed fibrate) could be life-threatening. In addition, at the time the Baycol prescribing information contained a warning regarding the use of Baycol in combination with fibrates.

Follow-up FDA Adverse Event Analysis Conducted

168. On or about October 1999, at the request of the Baycol Project Manager, Relator issued a second FOIA request to the FDA to obtain additional data on statin adverse events. Relator prepared an initial summary of the results. This information made an even more compelling case that Baycol differed from other statins in potential health risks. Relator passed on this information to Bayer's Drug Safety Department for further analysis.

Contraindication Added but Downplayed

169. In December 1999, Bayer acknowledged that there were specific risks involved with the use of Baycol in combination with gemfibrozil that should be disclosed and added a contraindication to the label. A letter notifying physicians and other healthcare providers of the contraindication was scheduled to go out in the first half of December; however, for unknown reasons, there was a delay in sending out the letter to at least some of the target audience. On or about December 17, 1999, product management discussed with Relator the benefits to Bayer of a delay because it was less

likely that the contraindication letter would be noticed due to holiday activities and mail delays. In addition, Relator is informed and believes that Bayer reduced the original target list of physicians and pharmacists, so that certain prescribers and pharmacists failed to receive notification of the contraindication.

170. Although Bayer placed a contraindication in the label, Bayer was also aware that physicians considered statins safe drugs and rarely consulted prescribing information. In addition, after the combination was contraindicated and the Bayer Healthcare Provider letter was sent out, Bayer intentionally avoided providing instructions to physicians regarding the meaning of the indication. Instead, Bayer employees and sales staff were informally advised that such decisions were "up to the physician."

171. Bayer did not clearly communicate to physicians that no new patients should be placed on a combination of Baycol and gemfibrozil until sometime in or about April 2001, shortly before the drug was removed from the market and significantly after the contraindication was added to the label. Physician requests for additional information regarding adverse events were essentially ignored with Bayer internally claiming that this information was unreliable.

172. In addition, although there was direction to the field to communicate the contraindication, the sincerity of the direction was questionable. Upon information and belief, the manner in which contraindication and labeling change were implemented demonstrated that Bayer was not sincerely attempting to communicate this important safety information to prescribers. As stated in one marketing presentation: "Less Said the Better."

173. In light of Bayer's commercial need to have Baycol perceived as similar to other statins, Bayer had sales representatives communicate to physicians that all statins had warnings regarding use in combination with gemfibrozil, and that Baycol was no different than other statins. Bayer did this despite its knowledge, based on the data in its possession at that time, including data provided by Relator, that it was extremely likely that Baycol had substantially different health risks than other statins, particularly with regards to use in combination with gemfibrozil.

174. On a number of occasions, product management representatives recognized that physicians were still co-prescribing Baycol and gemfibrozil and there were increasing adverse event reports. Relator suggested that Bayer could reduce the number of adverse events by clearly telling physicians not to use the two medications together in order to avoid the risk of complications. On each occasion, product management ignored these suggestions and continued with its deceptive marketing and "awareness" campaign.

Plans for a Fixed-Dose Combination with Fenofibrate Resulted in Diluted Warnings

175. One of the reasons that Bayer elected not to clearly and directly instruct physicians not to co-prescribe Baycol and gemfibrozil was that Bayer was actively investigating the creation of a fixed-dose combination of Baycol and fenofibrate (another fibrate drug). Indeed, during this time period, Bayer was conducting ongoing clinical trials of Baycol used in combination with fenofibrate (the "LDS" or Lipids in Diabetes Study) and intended eventually to launch a fixed-dose combination ("FDC") of Baycol and fenofibrate.

176. Bayer was conducting these trials even though: (1) Baycol labeling contained warnings against the use of Baycol in combination with fibrates; (2) there had been at least one reported adverse event where a patient using Baycol in combination with fenofibrate developed rhabdomyolysis; and (3) the prescribing information for fenofibrate (also known as "Tricor") expressly stated that the benefits of using Tricor in combination with statins did not outweigh the potential risks of severe myopathy, rhabdomyolysis and acute renal failure. Furthermore, a member of the Baycol Global team suggested getting Abbott Laboratories to amend the labeling for Tricor to facilitate pre-marketing of the LDS study as it was "obviously strategically important for Bayer to optimize our Baycol franchise for diabetics," and "US physicians are concerned about potential litigation."

177. The fact that Bayer was conducting such studies and promoting the combination further served to obscure and contradict the minimal and ambiguous warnings Bayer was providing to physicians about the dangers of using gemfibrozil in connection with Baycol, suggesting that Bayer believed that such use was, in fact, safe and appropriate, when it knew otherwise.

178. In September 1999, Relator was asked to evaluate the market potential of the Baycol-fenofibrate FDC tablet. Bayer believed that this FDC would command a premium price over the price of Baycol. After the contraindication with gemfibrozil was added, Relator communicated her concerns to global and U.S. marketing personnel regarding the marketing challenges and safety risks inherent with a contraindication with one fibrate (gemfibrozil) while promoting use with another fibrate (fenofibrate). Bayer disregarded Relator's concerns. Instead, Bayer continued to support the use of Baycol in

combination with fenofibrate and downplayed the risks associated with Baycol and gemfibrozil.[11]

Safety Considerations in End Stage Renal Disease Trial Ignored

179. Bayer disregarded patient safety in the development and evaluation phase of a proposed clinical trial of Baycol with patients suffering from end-stage renal disease ("ESRD"). Secondary research conducted by the Relator suggested that patients with ESRD were possibly at increased risk for complications when using statins. Given that Baycol currently experienced problems with rhabdomyolysis, Relator was concerned that Baycol might pose a unique risk to these patients. Bayer ignored this data, and proceeded with a clinical trial involving patients to try to document reduction of myocardial infarctions in this patient population. To Relator's knowledge, the potential risk to patient safety was never evaluated in a smaller population and the potential risks to patients were never disclosed to the participants.

Bayer's Misbranding of Baycol

180. Bayer's efforts to downplay safety concerns and strengthen the efficacy perception for Baycol resulted in a number of activities that constitute misbranding.

181. Starting in the Summer of 2000 with the launch of Baycol 0.8 mg, Bayer used the following statement throughout Baycol promotion, as being representative of

[11] Excerpt from 12/21/2000 Joint Development Committee minutes:
"Fenofibrate Labeling
A summary of the Baycol 0.3mg-fenofibrate study is being prepared to add the results to labeling. We will propose to add a description of the study results to the warnings/precautions sections of the label **to offset the gemfibrozil contraindication.** This data will be updated with results from FACTOR, when available. Similar results are presented in the pravastatin package insert."
(Emphasis added).

Baycol efficacy: "Baycol 0.8mg gets 84% of patients to NCEP[12] goal."[13] This was a misleading promotion.

182. Bayer failed to clearly disclose that many of the patients in this clinical trial were already at NCEP goal and/or not eligible for drug treatment using NCEP guidelines, thus overstating Baycol efficacy. For example, if only those patients who were considered eligible for drug therapy according to NCEP guidelines were evaluated, Baycol only got 75% of eligible patients in the trial to NCEP goal with Baycol 0.8 mg. Both Bayer and physicians providing market research feedback knew that claim would be too weak for Baycol to be considered competitive with Lipitor. Furthermore, the 84% claim is clearly inconsistent with the NCEP data provided in the FDA-approved label (Prescribing Information) and represents off-label marketing.[14]

183. As of the launch of the 0.8 mg dose in August 2000, the updated Prescribing Information for Baycol specifically stated that, "The recommended starting dose is 0.4 mg once daily in the evening." Even before the launch of the 0.8 mg dose, Bayer was aware of an increased risk for adverse events when using the 0.8 mg as a starting dose. Yet despite being faced with an ever-increasing number of reports of rhabdomyolysis (and deaths) associated with using the 0.8 mg as a starting dose, Bayer failed to adequately communicate to both sales representatives and health care providers the known safety risks until May/June 2001 (just before the withdrawal).

---

[12] National Cholesterol Education Program

[13] This data is based on the results from the Baycol 0.8 mg pivotal trial (Insull).

[14] The July 2000 prescribing information included the following statistics regarding the percentage of 0.8 mg patients to NCEP goal: Patients with <2 risk factors: 79%, patients with • 2 risk factors: 72%, and patients with CHD: 53%.

184. Federal regulations state that comparative claims between two drugs cannot be made without adequate support and documentation.[15] Bayer was reminded of this fact in an October 1999 warning letter from the FDA regarding claims against Pravachol. Despite this warning, Bayer went on to promote Baycol as having similar efficacy to Lipitor. For example, a Baycol sales aid from 2000 incorporated LDL-C results from a Baycol - Lipitor head-to-head trial. Bayer was unable to demonstrate that Baycol was non-inferior; however, results were graphed as favorably as possible and the conclusion was buried in the small text below the chart using a phrase akin to: "Baycol was not shown to be non-inferior."

185. Although the phrase was noted as confusing, it was still used as it provided Bayer the best opportunity to minimize the formal conclusion that Baycol was not as effective as Lipitor. Sales representatives used this material to deceptively claim that Baycol provided comparable efficacy to Lipitor.

Bayer's Continuing Misleading Deceptive Conduct

Baycol 0.8 mg Launch and Avoidance of Safety Issues

186. Bayer considered Baycol 0.8 mg as critical to the overall success of Baycol due to its greater efficacy and thus improved ability to compete in the statin marketplace.

187. Prior to the 0.8 mg launch in July 2000, Relator was present at an internal brand meeting, with Bayer Pharma's new President Dr. Wolfgang Plischke (who had just come from Bayer Japan), where he firmly stated "physicians will start on 0.4 milligrams and titrate to 0.8 milligrams." Although product management representatives were in

[15] Federal regulations typically require comparative claims between two drugs to be supported by **two** adequate and well-controlled clinical trials.

attendance at the meeting and knew, in fact, that market research suggested that many physicians were intending to start their patients on the 0.8 mg dose, no one contradicted this statement or indicated that it was inaccurate given senior management's significant emphasis on the success of the Baycol 0.8 mg dose.

188. Relator was involved in a number of conversations during this time period in which it became clear that Bayer believed it was in the company's best interest to disregard the fact that physicians were inclined to start on the 0.8 mg dose. Relator believes that Dr. Plischke was aware of safety risks of starting patients on the 0.8 mg dose. In August 2000, it was reported that the 0.8 mg dose in the Japanese bridging study and the Japanese long term safety study were stopped after experiencing 3 cases of creatine kinase ("CK") elevations indicating safety concerns.[16] After the launch of the 0.8 mg dose, research showed that a significant percentage of 0.8 mg use was, in fact, new patients.

189. Dr. Plischke reportedly also avoided other safety discussions. According to a member of the global Baycol marketing team who was also present at the meeting, Dr. Plischke participated in a meeting with an individual who was purportedly affiliated with the FDA.[17] When the meeting started, this individual began to discuss concerns about Baycol safety. When Dr. Plischke realized the topic, he abruptly announced that the meeting was over and walked out.

---

[16] CK is measured thorough use of a blood test. Elevated CK levels are suggestive of muscle or kidney damage; extremely high levels are used to diagnose rhabdomyolysis.

[17] This individual may have been Dr. Gerald Faich, a former FDA official, who provided consulting to Bayer on Baycol safety matters.

190. When the 0.8 mg dose was launched, all formal documentation indicated that a patient should be started at 0.4 mg and titrated up to 0.8 mg. However, Bayer representatives' informal and oral communications suggested that this was not necessary. For example, when queried about whether it was really necessary to start patients on 0.4 mg, the response was that "physicians are always free to do what they want." Through these various informal communications, various representatives of Bayer communicated to the physician population that it was acceptable and posed no additional patient risk to start patients on 0.8 mg.[18] While Relator did not discover that there was an actual

---

[18] Excerpt from David Ebsworth presentation at the Baycol withdrawal press conference August 13, 2001:

> Rhabdomyolysis is a rare but potentially life-threatening side effect that can occur in connection with any of the lipid-lowering medications commonly in use today. The risk is increased if statins are prescribed in combination with gemfibrozil. Gemfibrozil is also a cholesterol-lowering drug; generic forms are particularly widespread and frequently prescribed in the USA.
>
> Since simultaneous prescription of cerivastatin and gemfibrozil is known to increase the risk of side effects, we have included a warning to this effect in the prescribing information ever since the launch of our product. We later included a contraindication in the prescribing information and sent letters to doctors informing them of the situation. Nonetheless, in spite of all these efforts, we continued to receive reports of muscle weakness in patients who were taking both drugs at the same time.
>
> Data also indicates that, in comparison with other statins, muscle weakness appears to occur more frequently in patients given combination therapy with cerivastatin and gemfibrozil.
>
> Since as a company we cannot preclude the possibility of some doctors continuing with their usual prescribing practice, we have decided to take the product off the market voluntarily to avoid endangering patients.
>
> …"Our prescribing recommendations for the 0.8 milligram dose clearly states not to initiate therapy with the highest dosage; the patient should be started on a lower dose which should be increased gradually. **Unfortunately many doctors did not observe this important recommendation, and we felt that this incorrect use of the product represented an additional risk for patients."…**
>
> **Since, in spite of all our warnings, we could not be certain that the product would not be prescribed contrary to our recommendations, thus having potentially serious repercussions, we decided to stop marketing the product in the interest of the safety and health of the patients using it.**

concern or reason not to start patients on 0.8 mg dose until six months after the launch and after a significant number of adverse events had been reported, Relator believes that this information was known to senior management prior to the launch of the 0.8 mg dose.

Bayer's Contradiction Awareness Study Demonstrated Low Awareness of Contraindication

191. In August 2000 (just after the launch of the 0.8 mg dose and 8 months after the contraindication), Relator was requested to conduct a market research study regarding physician and pharmacist awareness and knowledge of the contraindication with gemfibrozil. At least as early as the launch of the 0.8 mg dose, Bayer was aware that there was likely to be eventual review of Baycol safety matters by the FDA. This expected FDA review was the driving force behind Bayer commissioning the contraindication awareness study. According to management, the objective of this study was to provide a baseline for awareness to help document to the FDA and legal community (when eventually the matter was scrutinized) that Bayer in fact was making progress at educating physicians regarding the contraindication. (During the design of this study, there were at least two questions that were not included as Bayer did not want documentation regarding the results. Specifically, the study did not document how and when the physicians or pharmacists learned about the contraindication.)

192. Although there was surprise internally at Bayer at just how low the contraindication awareness in the market was, Relator is unaware of any additional education or communication efforts implemented as a result of this information. In fact,

---

> We are currently aware of 52 fatalities, including 5 in Germany, which are said to have occurred following treatment with cerivastatin and the occurrence of rhabdomyolysis. These cases are based on spontaneous reports, which – as the authorities have also repeatedly emphasized – have only limited conclusiveness.

(Emphasis added).

Relator made a recommendation in Spring 2001 to not conduct a second study at that time, given that Bayer had done nothing that would have resulted in a significant change from the previous results.

Perceptual Studies Demonstrated Bayer Successful at Deceptive Marketing Strategy

193. In conjunction with Princeton Brand Econometrics, Relator conducted a monthly "Awareness, Trial and Usage Study" ("ATU") that tracked physicians' usage and perceptions of Baycol and other statins starting just after launch. As part of this study, Relator tracked the perceived appropriateness of using Baycol in combination with gemfibrozil starting in October 2000. It was clear from this study and the lack of movement of the results over time that Baycol was perceived as similar in safety to other statins, that physicians perceived that it was okay to use in combination with gemfibrozil, and that any message to physicians was not changing these perceptions. Relator concluded that in order to stop co-prescribing, the combination had to be perceived as inappropriate and that was not going to happen unless: (1) other statins were shown to have a substantial risk of complications when used in combination with gemfibrozil; or (2) Bayer was willing to admit that they had an increased risk of adverse events when compared to other statins and/or that there was a significant risk of adverse events when using Baycol in combination with gemfibrozil. Relator clearly communicated these conclusions to senior management at Bayer on several occasions and their response was that they did not believe modification of their practices was necessary.

194. The Baycol Global Strategic Management ("GSM") team conducted a similar international perceptual study with prescribing physicians in Spring 2001, working with P/S/L, a marketing and communications vendor. These efforts were

coordinated by Kevin Brubacher from Bayer GSM. During the design of the study, it became apparent to the Relator that the Baycol global marketing team wanted to make sure that Baycol was perceived as similar to other statins with regards to the attribute ”Suitable in Combination with Gemfibrozil” despite the fact that, by this time, the results of the Pacificare study had clearly shown that Baycol has a substantially worse interaction profile with gemfibrozil than other statins. At the same time, GSM was striving for Baycol to be perceived as superior to other statins on the attribute ”Suitable in combination with fenofibrate” to facilitate the development of a market for the Fixed Dose Combination of Baycol with fenofibrate. Results of the P/S/L Baycol perception study (August 2001) showed that Bayer had been relatively successful at making sure Baycol was perceived on both attributes as relatively similar to other statins, particularly with primary care physicians.

Physician Message Recall Study Suggests Safety Messages Not Being Communicated

195. In Fall 2000, Relator conducted a message recall study to understand physicians’ perspectives on the messages being communicated by sales representatives. Bayer’s management was interested in how effectively Baycol efficacy was being communicated to physicians. From this study, it was clear that the contraindication was not being consistently communicated to physicians. At the time, physicians reported that there was mention of a contraindication on only a fraction of Baycol details. Research also showed that the 0.8 mg dose was not being clearly positioned as a titration dose. Although this information was communicated to Product Management, no action was taken.

Efforts at Downplaying Risks Continued

196. Sometime between the summer of 2000 and the withdrawal of Baycol (est January 2001), there were meetings with the field force that included presentations by Roger Celesk (Associate Director of Drug Safety) to sales representatives regarding the potential dangers of developing rhabdomyolysis as a result of taking Baycol. Mr. Celesk felt that it was important that sales representatives be informed of the seriousness of potential adverse events. After Mr. Celesk's initial presentation, Bayer's Senior Vice President of Sales and Marketing, and Vice President of Cardiovascular and Metabolic Marketing, who "did not want to alarm sales representatives," replaced Mr. Celesk with an alternative speaker who presumably did not address the seriousness of potential adverse events.

Deceptive Marketing Demonstrated at Bayer Global Marketing Meeting

197. In February 2001, Relator was present at a Bayer global marketing meeting that featured a breakout session specifically for Baycol personnel in which numerous deceptive and false statements were made. For example, statements were made suggesting that Baycol was superior and substantially safer than Lipitor. At the February 2001 meeting, data and results were discussed that the Relator knew to be inaccurate based on Relator's personal knowledge. This misleading data was incorporated into the Key Messages for the product, and was intended to be used for promotional use. Relator complained about the use of this data but was indirectly informed that it was not Relator's concern and to stay out of it.

198. Much to the surprise and concern of the Relator, very little (if anything) was said about the safety concerns of Baycol at the global meeting, although Bayer's

management was well aware that there were substantial safety issues. In fact, the key global messages listed for Baycol included only positive safety messages such as low risk of drug-to-drug interactions.

199. Around this time, Eric Pauwels, Global Strategic Marketing Director for Baycol, made the statement "I never met a database I didn't like." The clear implication of this statement given the context in which it was made was to further support that Bayer was cherry-picking and/or manipulating data to make it appear that Baycol was a more appropriate therapeutic alternative than was in fact the case. Relator in fact made several attempts during this time to obtain raw clinical data on Baycol because the marketing claims and data from Global were suspect. For example, it was common to conduct clinical trials and include participants who were already at their cholesterol goals. When the results were calculated about the percentage of patients who reached goal with a given dose, the patients who were at their goals before the study even started were included in the results.

Stopping Distribution of 0.8 mg Samples: Downplayed Risks

200. In March 2001, there was an internal Bayer recommendation to stop providing 0.8 mg samples to physicians given that they were being used for patient starts. In April 2001, Relator was asked to review the text of a draft voice-mail message to the field communicating that no more 0.8 mg samples were going to be shipped. In Relator's opinion, the text of the message did not appropriately focus on the significant concerns about patient safety and the risks involved with starting on a 0.8 mg dose. Relator made the recommendation to clearly communicate to sales representatives that there were

associated risks with starting patients on a 0.8 mg dose of Baycol. To Relator's knowledge, no significant changes were made to the message.

Manipulating the 0.8 mg Sample Inventory Assessment

201. In May 2001, Relator was asked to conduct an analysis ("audit") to determine the projected sample inventory levels in the field, based on a mandate to Conger by the APZ (Safety) committee. Relator now believes that this analysis was requested to determine if the 0.8 mg samples should actually be recalled or if inventory levels were low enough that they would be depleted before a recall could be accomplished. Conger, Bayer's Vice President of Cardiovascular and Metabolic Marketing looked at the initial inventory estimates, expressed concern and alarm, and then requested that the analysis be redone with specified revised assumptions. Relator was directed to not show the initial analysis to anyone else. Although Relator did not agree with the new assumptions and felt that the results were being purposely and fraudulently manipulated, she did agree to revise the report. The result of redrafting the report with the revised assumptions was that there was less estimated sample inventory out in the field with drug representatives than had initially been projected. Relator believes Conger used this revised report to document that a 0.8 mg sample recall was unnecessary, and distribution of existing inventory of Baycol 0.8 mg samples to physicians could continue as they would soon be depleted.

202. When the FDA subsequently expressed concerns over Baycol safety, Bayer told the FDA that they had stopped sampling Baycol 0.8 mg which was false and/or misleading. What Conger did was to stop shipping 0.8 mg samples to sales representatives, while letting them continue to distribute existing 0.8 mg sample

inventory to physicians. After the withdrawal, Conger maintained that Bayer continued to provide 0.8 mg samples to physicians up to the withdrawal and he never intended to stop sampling the 0.8 mg dose to physicians.

203. Throughout this time period, even into May 2001, Bayer was continuing to represent both formally and informally, as part of its marketing campaign, that Baycol had a "proven safety and tolerability profile" and a side effect profile similar to other statins even though the data in Bayer's possession at that time clearly indicated the opposite. In fact, in May 2001, Julie Green, Director of Baycol Marketing, gave Relator proposed Baycol positioning statements[19], which clearly and falsely suggested that Baycol safety was similar to other statins. Even at this late date, Bayer was still trying to deny a known safety problem with Baycol.

Management Showed a Pattern of Avoiding Action

204. Although it was well aware of safety concerns regarding higher interaction rates of Baycol with gemfibrozil early on, Bayer did not conduct the relevant pharmacokinetic (pk) studies until in or about 2001. Those studies demonstrated that there was a clear interaction between the drugs resulting in dangerously high levels of cerivastatin (Baycol) when used in combination with gemfibrozil. The interaction studies that *were* conducted for Baycol were typically proposed and discussed as additional means of promoting Baycol.

205. During her employment, Relator observed other examples of "considered ignorance" by Bayer's senior management. For instance, in response to a recommended clinical/safety trial of another Bayer drug that might have potentially negative results,

[19] A brand positioning statement is intended to succinctly describe how the marketer wants the target audience to view the brand.

Paul MacCarthy, Bayer Medical Director and key member of the Bayer Global Safety Committee (with responsibilities for Baycol and author of the Baycol withdrawal letter), stated in Relator's presence, during a June 2004 internal planning meeting, in words or substance "We don't have to tell them [FDA] what we don't know." The clear implication was that Dr. MacCarthy was recommending against conducting the proposed trial because he was concerned it might reveal safety concerns that Bayer would have to disclose about the drug. Based on Dr. MacCarthy's recommendation, Bayer decided not to conduct the trial.

206. Relator also observed this type of attitude by senior management throughout the time period that Bayer was marketing Baycol. In fact, when Relator expressed concerns about Bayer's behavior relative to Baycol, Bayer's Vice President of Cardiovascular and Metabolic Marketing expressed that they were "doing everything we are legally required to do." Relator inferred that this meant that because Bayer made some labeling changes and had taken steps necessary to make it appear that they were concerned and taking action, further (and more effective) efforts were considered unnecessary.

Baycol Kickbacks and Fraudulent Marketing Claims

207. In addition to its unfair and deceptive marketing practices designed to increase Baycol's market share, Bayer also used payments and benefits to providers and healthcare organizations in order to induce them (directly or indirectly) to begin prescribing or increase their prescriptions of Baycol.

208. Bayer paid illegal kickbacks to healthcare providers who purchased and/or administered Baycol, and thus caused them to falsely and expressly and/or impliedly

compliance with the Anti-Kickback Statute, and to seek reimbursement from Medicare, Medicaid, and other government programs for such false claims.

209. At the September 1998 Brand Review Meeting (discussed earlier), Dr. Ebsworth proposed a "switching seeding trial" program to encourage Baycol prescriptions. As a result, Bayer implemented the CREST ("Cerivastatin Response Experience as Standard Therapy") program with Baycol 0.3 mg in Spring 1999. The program paid physicians to participate in the trial and then discuss results. Bayer designed this program with the specific intent to increase Baycol prescribing among high-decile[20] statin prescribers.

210. Bayer developed the scientific study objective to determine if there was a link between Body Mass Index and the response to the Baycol 0.3 mg dose *after the fact* to justify paying physicians to place patients on Baycol.

211. Bayer's specific marketing objectives were to determine: "Do Therapeutic Circles impact Baycol prescription volume of participating investigators?" and "Will Therapeutic Circles alter the perception of Baycol?"

212. Bayer was extremely interested in determining whether these programs were achieving their stated objectives of significantly increasing Baycol market share, and thus warranted further expansion of the programs. To evaluate the programs, Bayer conducted Return on Investment ("ROI") analyses relative to CREST.

213. Sales representative feedback on the benefits of the CREST programs included "conversion of No-See physicians; early increase of Baycol sales in their territories, and equivalence of 5 years of relationship building with MDs in their

[20] Measurement of prescribing activity with high deciles being the highest prescribers and low decile physicians prescribing less frequently.

territories." The CREST programs were used in conjunction with encouraging uptake in the Pacificare health maintenance organization in Fall 1999. These CREST programs were precursors to substantially larger Phase IV seeding trials conducted in late 2000 and 2001 -- CRISP and CHARGE.

214. As it did in connection with other marketing campaigns for its drugs, Bayer paid physicians, more than 6000 of them, to attend group meetings (known as Clinical Advisory Panels ("CAP")) to listen to a clinical presentation and discuss their experience with Baycol. (*See* Exhibit A for a CAP Attendee List with time and date of programs attended, where false and misleading information was communicated).

215. Carol Clark, Baycol Product Manager, oversaw the CAP programs and worked in conjunction with Gayle Reinhart from GlaxoSmithKline to implement the programs. Carol Clark reported to Michael Matin, Director of Cardiovascular Marketing from September, 1999, through May, 2000, and later to Conger, Vice President of Cardiovascular Marketing who worked on Baycol from Summer of 2000 until after the withdrawal. They hired a vendor--Boron Lapore--to implement the programs.

216. CAP programs were started in 1999 and continued up to the withdrawal.

217. Bayer controlled the content of the CAP programs, trained the speakers, and provided false and misleading information to attendees. For example, the 2000/2001 CAP program provided the following information to attendees as a key message:

> In patients with no risk factors, NCEP goals are met by:
>
> 81% using Baycol 0.4 mg
>
> 90% using Baycol 0.8 mg
>
> In patients with CAD [coronary artery disease], NCEP goals are met by:

41% using Baycol 0.4 mg

59% using Baycol 0.8 mg.

218. Pharmaceutical firms are able to state the results of specific clinical trials; however, they cannot make claims that this is a representative or an expected result without adequate supporting evidence. Because Bayer included patients already at National Cholesterol Education Program goal in the clinical trials used as the basis for these claims, Bayer cannot legitimately claim that "NCEP goals are met by 59% using Baycol 0.8 mg" as this implies that 59% of patients who qualify for statin treatment under the guidelines would meet NCEP goals using Baycol 0.8 mg -- an inaccurate claim. Bayer did not have evidence to support ***any of the marketing claims*** as phrased above. Simply put, these marketing claims are fraudulent and constituted misbranding. In addition, these claims also constituted off-label marketing as the information was inconsistent with the labeling which stated, for example, that in patients with CHD 24% of patients reached goal with Baycol 0.8 mg and 79% of patients with no risk factors reached goal with Baycol 0.8 mg.

219. This so-called "market research" or "consultant advice" was merely a conduit to pay thinly disguised kickbacks which Relator has personal knowledge were primarily intended by marketing to increase Baycol's market share and were not intended to gather valuable market research or advice as was represented to the public. Bayer knew that this conduct was not legitimate market research and/or advice when it presented it as such and instead used these meetings to increase the legally questionable prescribing for the drug. Bayer's objective is best exemplified by an internal statement to sales representatives that: "The overriding goal of this program is to support and

supplement your selling efforts and ensure key customers hear and understand the BAYCOL message." ROI analyses conducted for these programs showed that market share per physician increased from 3 - 5% after participation.

220. In 2000, the budget for CAP programs was $3 million with 180 sites planned. The budget for CAP in 2001 was $2.7 million; the budget was presented with the caveat that the ROI for the programs would be assessed and if the return was not positive, certain of these funds would be reallocated.

221. Bayer selected and trained 100 - 200 top prescribing physicians as speakers for these programs. The speakers received travel, meal, and other expenses in addition to honoraria. Bayer specified $1,000 as speaker honoraria for these programs.

222. In addition, Bayer instituted Baycol Experience Programs where high volume prescribing physicians received free 30-day sample packages of Baycol (full prescriptions) to encourage physicians to place new patients on Baycol. More than 70,000 Baycol sample packages of various sizes were designated for this program or variations of this program. (These or similar programs occurred with both the launch of Baycol 0.4 mg and the launch of Baycol 0.8 mg).[21] Physicians were selected by sales representatives based on an assessment of their propensity to increase the number of prescriptions written for Baycol. Some of these physicians were from organizations where there was risk-sharing for pharmaceutical benefits which meant that they could personally benefit from free or reduced price pharmaceuticals.

223. As part of Baycol's Experience programs, selected physicians were invited to attend dinner meetings to discuss their experiences and "be fully exposed to all aspects

[21] For the 0.8mg launch, this program was called the Baycol Experience Challenge or BEC.

of the Baycol message." In addition to receiving dinner for participating in the program and placing patients on Baycol, physicians also received a consulting honorarium or other compensation.[22]

224. For example, Bayer implemented a Post-Launch Experience program where physicians were reportedly paid $750 each to participate by placing their patients on Baycol and discussing their findings with Bayer. These payments, in addition to those mentioned above, constituted illegal kickbacks whereby Bayer paid doctors to increase the market share for its drugs. Relator was asked to participate in analyzing the ROI for certain of these programs.

225. In 2001, Bayer initiated a "Free Product Promotion Initiative" which provided physicians with certificates for free 30-day samples of Baycol to high statin prescribers affiliated with selected managed care groups. In a letter to drug representatives in the field, Project Management cites benefits of this program such as: "increased access/sales for Baycol" and "significant cost benefit for physicians with pharmacy risk." This clearly conveyed a physician benefit for prescribing Baycol as doctors needed to issue prescriptions to redeem sample certificates. Under this program, each physician was to receive ten certificates. Bayer's selection criteria included factors such as "areas with recent regional HMO formulary wins that need additional support to drive share." Notes to the field in Q and A format specify that **anyone can use the certificates** "although we are discouraging the use of these cards for Medicare or Medicaid patients for legal reasons." Bayer planned ROI analyses for these initiatives as well.

[22] Between October and March 2001, 167 Baycol Experience Challenge Dinner Programs were held with 2,514 attendees.

226. In the Baycol Business Plan for 2001, the Tactical plan for Specialists identified a key marketing tactic as "Focus detailing and promotional resources on highest potential physicians." Product Management specified that national and regional advisory boards would be used in support of these tactics with the expectation they would drive Baycol sales. Regional consultant conferences were budgeted at $1.3 million in 2001. In each of these instances, physicians would have received an honorarium.

227. A "Group Practice Regional Roundtable Push/Pull Program" was also described with the objective of "driving share upwards through physician group practice partnerships" for large group practices "at risk" for pharmacy benefit. Upon information and belief, physicians were paid an honorarium for participation in these promotional activities as well.

228. In the 2002 Brand Plan, one of the key issues was to "[c]reate more Baycol Loyalists." One of the identified key tactics was to "[c]ontinue focus on present 'Baycol Loyalists' through opportunities in Phase IV, speaking opportunities etc.," a clear reference to potential financial and other benefits of continuing to prescribe Baycol. In addition, Bayer created a Baycol Advocate List of 500 physicians and then directed that "Every effort should be made to involve these key Baycol advocates in field programs." Areas of involvement specifically identified were the "ACC[23] Social Event, Regional NCEP programs, CAPS programs, and CHARGE[24] Phase IV trial."

229. Bayer also paid a $100,000 annual retainer fee to Antonio Gotto, MD, a key opinion leader in lipids, to promote the use of Baycol. The value of this service was

[23] Bayer sponsored a social event for physicians at the American College of Cardiology.

[24] CHARGE was a large Phase IV clinical trial designed specifically to increase Baycol prescribing by specialists.

noted by product management as having waned, and there were questions why Bayer was continuing to pay Dr. Gotto this fee.

230. Relator also participated or was familiar with other programs involving kickbacks and false and misleading information. For example, Relator was involved with assisting and mentoring Paul Fletcher, a new and relatively inexperienced Baycol Product Manager assigned to develop and oversee the 2001 Strategic and Tactical Plan for Baycol, which was eventually presented to Bayer Senior Management -- such as Karen Dawes, Sr. Vice President of Sales and Marketing, and Dr. Wolfgang Plischke, CEO -- for their comments and approval. In addition to Brand Review meetings, Relator also participated in Strategic and Tactical planning meetings where a large number of promotional program concepts were proposed, discussed, evaluated and prioritized for further work. Selected programs were compiled into the annual Tactical Plan and program costs were incorporated into the Baycol Advertising and Promotion (A & P) as budget line items. Relator worked with Mr. Fletcher to develop the slides for tactical programs which he and other Baycol marketing and Scientific Affairs personnel conceptualized. Mr. Fletcher requested that market research conduct Return on Investment analyses for a number of these programs. In order to design these analyses, Relator was required to have knowledge of how the programs were set up, including their costs and expenses. Upon information and belief, additional examples of kickbacks, which occurred at the individual physician-level as well as in managed care and institutional settings, included:

a. **Physician Medical Group (PMG) Advisory Panel Program**. This was a program whereby key personnel from important groups were compensated to

attend events designed to increase the use of Baycol. Relator was familiar with this program as part of the 2001 Tactical Plan for Baycol.

b. **Expense-paid trips for selected opinion leaders to attend Bayer and industry symposia and/or conferences**. For example, 600 specialists and opinion leaders attended Baycol 0.8 mg regional launch symposia in October and November 2000, which upon information and belief, involved not only payment for expenses but honoraria as well to attend the event. Sponsored selected opinion leader attendance at a number of international conferences/symposia as well. (*See* Exhibit B for example of Baycol Opinion Leader List). Relator discussed these meetings and how they should roll out as part of the Joint Marketing Team and Baycol Project Teams, and was provided the Opinion Leader list for market research Phase IV studies (and associated funding) whose purposes were to "attain managed care listing or further drive business." The funding for Phase IV studies came out of the marketing A&P (advertising and promotion) budget. Once again, the CREST Phase IV (seeding) trials were also used to drive Baycol use with Pacificare physicians, and Relator was familiar with this intent and the programs as a result of her participation in marketing meetings and participation in ROI analyses.

231. Relator also reviewed protocols related to CRISP and CHARGE - two large Phase IV (seeding) clinical trials, and provided ad-hoc input into CHARGE. Relator was informed of the marketing objectives of these trials, prior to their design, by Baycol Senior Management including Dr. Ebsworth, who felt that cardiologists needed additional incentives to use Baycol. Similar to the CREST study, the medical rationale for conducting the study was developed after the decision was made to conduct the seeding trial to encourage Baycol use. For example, the purpose of CHARGE was to

drive use of Baycol by cardiologists, and Conger requested Relator to identify high prescribing cardiologists for recruitment as ”paid investigators.” Relator worked with Gina Criscuolo, a secondary data analyst on Baycol, to provide these lists to the marketing department. The CHARGE protocol was designed to be misleading as it limited patients to only those with lower cholesterol levels (*i.e.*, less severe and thus easier to treat patients) and also allowed into the clinical trial patients already at NCEP goals. Conger and other Bayer marketing personnel kicked off the trial via teleconference to Baycol sales personnel. Bayer planned to use these results to demonstrate ”the outstanding ability of Baycol to get patients to NCEP goal.” [25]

232. “No See” cardiology programs were expense-paid weekends for difficult to see cardiologists set up as continuing education programs with the actual objective of increasing Baycol sales. Relator was familiar with these programs and Brand Management objectives for the programs as part of the tactical plan for Baycol.

233. Paid switch programs and switch studies, in which Bayer provided funding to some Managed Care Organizations, lipid clinics, and government organizations to develop and implement switch programs or conduct clinical studies related to switching patients to Baycol from other statins. Relator participated in discussions related to these programs as part of the Joint Marketing Team meetings, and Baycol Product Management meetings. Relator was familiar with the Walter Reed Army Medical Center Switch study funded by Bayer from internal discussions, reviewing the draft protocol, and draft journal article after the trial was completed, and market research. Some of these programs were also part of the Tactical Plan for Baycol which Relator helped develop in conjunction with her work with Mr. Fletcher and others. Relator

conducted physician market research based on the clinical and/or financial results from some of these studies such as the Madigan retrospective switch study and the Spaar switch study (two other Dod Switch studies). In general these studies were misleading as they incorrectly attributed increased NCEP goal attainment from switching statins to Baycol efficacy rather than to temporarily increased compliance that such switches generate, among other issues.

234. Free goods in the form of large quantities of samples were given to induce prescribing in managed care organizations (while also reducing their prescription costs). For example, Bayer sent at least one free drum of samples (*i.e.*, more than 450,000 tablets) to PacifiCare at the beginning of the contract. Quantities provided were contingent upon the contract and not available to all prescribers or organizations equally. Relator learned about these efforts as a leader and/or participant in various projects and discussions related to assessing Baycol sample requirements.

235. P&T (Pharmacy and Therapeutics) Consultancy Forums were regionally based meetings designed to reach key "P & T committee influentials." Participants received honorarium and expenses in exchange for listening to a Baycol presentation and providing advice on how to get Baycol on the respective formulary. Relator reviewed the results of some of these meetings, and was asked to provide input by Patricia Stenger, Scientific Affairs, related to discussion questions. Relator also used the participant lists from some of the meetings in recruiting participants for a managed care pricing study for Baycol. Relator was also familiar with these programs as part of the Tactical Planning process.

236. Bayer's Baycol Textbook Program provided a physician with a choice of textbooks and was used by sales representatives to "further cultivate strong relationships with [physicians]." The program was described as a "useful tool" to "focus on the 'hard to see' physician." Relator was familiar with the program through discussions with Baycol brand management, and from assisting Baycol product managers in evaluating textbooks for distribution.

D. Baycol Claims

Examples of Patient-Level Claims

237. Adverse event reports provide examples of Baycol use and patient-level claims in the DoD.

238. On January 12, 2000, Zygmunt reported to David Rose that Karen Schreiber, RPh Tyndall Air Force Base, Tyndall FL 32403, reported that a patient of Dr. Neal Beightol was admitted to the hospital with a diagnosis of myositis. Schreiber reported as follows: [Patient] N.C. is a 56 y/o female with a Hx of Hyperlipidemia and was on Baycol 0.3mg since Nov. 99. She started to experience muscle aches and pains approx. 1 week ago which has gotten progressively worse. . . . Attending physician at the base is Dr. Neal Beightol. The Attending physician off base is Vickie Harrell, MD. . . Baycol is being attributed as the cause of this patient's myositis." Schreiber further noted that Dr. Harrell attached a note to N.C.'s chart about 2 patients in her practice that were hospitalized with rhabdomyolysis while also taking Baycol.

239. One military health care program recipient, a 56 year-old male**,** with a date of birth in November 1932, who had been prescribed pravastatin and gemfibrozil was switched to Baycol 0.4mg for the period October 22, 1999, to January 27, 2000. On or

about January 30, 2000, he was hospitalized with rhabdomyolysis according to personnel at the Pharmacy Operations Center at Elmendorf Air Force Base, Alaska.

240. Another military health care program recipient, a 43-year-old male was prescribed Baycol 0.4mg twice daily by his private physician on January 12, 2000. He was also on concurrent gemfibrozil 600 mg twice daily, which was started on December 10, 1999. On February 13, 2000, he was hospitalized for two days at Eglin Air Force Base and both Baycol and gemfibrozil were discontinued on February 13, 2000. This incident was reported by Captain Reinaldo Morales.

241. On November 1, 1999, a 75-year-old female DoD patient was switched from Lipitor to Baycol and continued an existing prescription of gemfibrozil. On November 25, 1999, she developed severe muscle aches and lost the ability to walk. On December 4, 1999, she was admitted to the Womack Army Medical Center at Fort Bragg, North Carolina.

242. H.K., a 62 year old male in the Air Force, was started on July 12, 1999, on gemfibrozil 600 mg two times per day ('BID') and pravastatin (Pravachol) was added. He continued on this combination for six months. On January 11, 2000, the patient was prescribed Baycol 0.4 mg daily and the pravastatin was discontinued. On February 29, 2000, after experiencing muscle symptoms for approximately a week, the patient presented to the Emergency Room at David Grant USAF Medical Center at Travis Air Force Base and was diagnosed with rhabdomyolysis.

Government Payment of Claims for Baycol

Federal Claims

243. From October 2000 through the time of the withdrawal of Baycol from the market in August 2001, government agencies, under various contracts with Bayer for the supply of Baycol, including the DoD, Coast Guard, Indian Health Service, Veterans Administration and Federal Prisons, paid Bayer at least $11,983,305.08 for their supplies of Baycol.

244. According to the DoD PEC, there were approximately 400,000 Baycol prescriptions filled in MTFs during the period commencing October 2000 to the withdrawal of Baycol from the market.

245. In addition to claims made under the National Statin Contract, there were government purchases made under the Federal Supply Schedule for Baycol. For example in July 2001, Baycol 0.8 mg purchases (90 tablet bottles) were made by Brooke Army Medical Center (23 bottles) for $1,035.00; Charleston Naval Hospital (24 bottles) $1,080.00; Madigan Army Medical Center (84 bottles) $3,780.00; various government Medical Supply Officers: (20 bottles) $900; (12 bottles) $540; (108 bottles) $1620; (36 bottles) $540; (9 bottles) $405; National Naval Medical Center (50 bottles) $2,250; Naval Hospital (25 bottles) $1,125; 45th Medical Group (127 bottles) $5,715.

246. The Public Health Service ("PHS") also paid for Baycol. For example, in July 2001, PHS contract purchases were made by Gouveneur Hospital (12 bottles of 90 tablets) $983.28; Arrowhead/San Bernadino County Med Ctr PHS (138 bottles of 30 tablets) $3,768.78; University of California/San Diego (6 bottles of 30 tablets) $163.86; University of Nebraska (5 bottles of 30 tablets) $136.55.

247. As reported in early 2001, TRICARE expenditures from Tricare Managed Care Support Contractors for Baycol, presumably for Q42000 were: Tricare/Tricare West $42,622, Foundation Health System $221,810; Anthem $45,344; Sierra $28,431; Humana $378,059. In Spring 2001, 1.5 million beneficiaries were added to the TRICARE benefit program.

248. Drug costs under the TRICARE Senior Pharmacy program were pass-through (not-at-risk) costs to the Managed Care Support Contractors (MCSC). In other programs, TRICARE MCSC's shared pharmacy expenditure risk with the DoD.

Medicaid

249. Costs for pharmaceuticals covered under Medicaid are shared by the individual state and the federal government.

250. For Medicaid patients receiving prescriptions as outpatients, physicians typically write a prescription for the patient who then brings or sends it to the pharmacy to be filled. Once the drug is dispensed, a claim is generated. The pharmacy then submits these individual claims to the Medicaid program for payment. Later on, Bayer provides a Medicaid rebate to the states to reflect "Best Price."

251. From October 2000 to the time Baycol was withdrawn from the market, the Federal Government expended at least $2,545,600.84 for the federal participation portion for prescriptions of Baycol reimbursed through states' Medicaid programs.

252. From October 2000 to the time Baycol was withdrawn from the market, the following State Governments expended in total at least $2,151,515.94 for the state participation portion for prescriptions of Baycol reimbursed through Medicaid programs as follows:

California expended $702,995.80
District of Columbia expended $4,108.64
Delaware expended $7,558.47
Florida expended $502,850.59
Hawaii expended $9,513.29
Illinois expended $154,262.32
Louisiana expended $40,534.10
Massachusetts expended $70,039.06
Nevada expended $11,224.51
New York expended $429,752.73
Tennessee expended $52,993.26
Texas expended $165,683.69

253. In addition, the state of Florida made direct purchases of Baycol from Bayer in the amount of $38,577.64 during this time period. Florida gave Baycol "preferred status" under a contract with Bayer.

254. Attached hereto as Exhibit C are the Medicaid reimbursement totals, showing the quarterly reimbursement from selected states Medicaid programs, including the number of prescriptions, total number of reimbursed units (tablets), package size code, and tablet dosage.

Claims Summary

255. Thus federal and state government expenditures for Baycol from October 2000 to the time Baycol was withdrawn from the market were at least $16,718,999.50.

256. These figures do not capture other federal government expenditures for Baycol such as indirect payments related to Secure Horizons patients (a Pacificare health plan involving millions of Medicare beneficiaries).

257. Upon information and belief, non-contracted government expenditures such as DoD prescriptions purchased at retail pharmacies (network and non-network) are not included in the figures above as well as other government claims such as Federal Employees Health Benefits Plan beneficiaries.

Senior Management Aware of the Link between Marketing and Government Claims

258. Senior management at Bayer, such as David Ebsworth, Head of the worldwide Pharmaceutical Business Group of Bayer AG; Wolfgang Plischke, Executive Vice President, Bayer Corporation and President, Pharmaceutical Division, North America; Karen Dawes, Senior Vice President, Marketing and Sales, and Tig Conger, Vice President of Cardiovascular Marketing, were aware that government payors such as Medicaid and the DoD directly or indirectly paid for a significant proportion of Baycol prescriptions. DoD patients reportedly represented 20% of Baycol prescriptions in 2001.

259. For example, in early August 1999, just before the DoD contract was awarded, Dr. Ebsworth was informed by T.J. McKinney, another member of Senior Management, of "what we're doing to circumvent some of the restrictions that the DoD/VA had in place." He further stated that we "have established .4 as equal or better than our competitors products on a clinical basis," something which was not true at the time.

260. Bayer senior pharmaceutical management and Baycol Brand Management were responsible for Baycol profit and loss which included sales to government entities. Marketing plans were created to drive use in different market segments such as the DoD, TRICARE and Medicaid. Some of these segments such as the DoD were the focus of targeted marketing plans. Bayer marketing considered the spillover effect from DoD, Medicaid and managed care prescribing on other market segments (*i.e.*, targeting one market segment has a tendency to positively impact prescribing in other segments). Relator and other market research personnel for Baycol provided payor mix analyses to senior management such as Karen Dawes and Tig Conger, further demonstrating an

awareness by management that Baycol misbranding and marketing tactics would effect government claims for Baycol.

E. Baycol Withdrawn from Market

261. Despite the actions taken by Bayer described in this Amended Complaint, including the payment of illegal kickbacks to increase market share and the attempts to mislead the public as to the efficacy and safety of Baycol, as a result in part of an increase in adverse events as Bayer's market share increased, Bayer was forced to withdraw Baycol from the market.

262. Relator first learned in late Spring of 2001 that there were a significant number of deaths that were believed to be caused by the use of Baycol. Relator is informed and believes that senior Bayer personnel knew of this long before but failed to disclose it to the rank and file Bayer employees. Because Senior Bayer Management failed to provide relevant safety information on Baycol to many of Bayer's employees, to physicians, pharmacists, the American public, and the Government, Baycol was prescribed in amounts that it would not have otherwise been prescribed and patient safety was jeopardized.

263. In or about July 2001, the FDA required Bayer to address the problems with Baycol, particularly the 0.8 mg dose. As a result of the FDA intervention, Relator had discussions with Bayer senior management regarding the viability of the brand given the safety issues. Rather than being motivated by safety concerns, Bayer believed that the brand would not be commercially viable if the 0.8 mg dose was withdrawn and the lower doses remained, and felt similarly about a black box warning. Based upon

substantial safety concerns raised by the FDA, Bayer withdrew all forms of Baycol from the market in August 2001.

V. CONCLUSION

264. Upon information and belief, Bayer had in its possession information which if fully disclosed to Government would have resulted in Baycol not becoming an approved drug in the United States and/or being withdrawn from the market significantly before the time when Bayer implicitly acknowledged the dangers of the drug by voluntarily withdrawing Baycol from the market in August 2001. As a result of its failure to fully disclose information about Baycol to physicians, Bayer caused those physicians to prescribe the drug when they would not have otherwise done so.

265. Bayer's efforts to omit or downplay risk and adverse incidents with Baycol and to imply Baycol had comparable efficacy to Lipitor constitute misbranding under federal laws and regulations. Bayer's misbranding caused false claims to be submitted because the physicians relied on Bayer's assertions when they prescribed Bayer. Thus, but for Bayer's misbranding, thousands of patients and the Department of Defense would not have submitted such claims to the government, and the government would not have paid these claims.

266. As a result of Bayer's widespread improper conduct perpetrated upon the United States Government and ultimately the American public, the Government purchased and/or reimbursed significant quantities of Baycol when it would not otherwise have done so if Bayer had fully disclosed the truth regarding the safety of its drug. Bayer caused false claims to be submitted by patients and organizations because physicians relied on Bayer's assertions when they prescribed Bayer, thus causing false

claims to be submitted to the Government because had the Government known the full truth it would not have paid the claims.

267. Had Bayer been forthcoming to physicians and the American public, the Government would have purchased substantially less, if any, Baycol.

268. Bayer knowingly made false statements to get claims paid because it knew and intended that the Government would reimburse physicians and pharmacists for dispensing Baycol because of the misrepresentations that Bayer made regarding its safety and efficacy.

269. It was foreseeable that Bayer's conduct (including misleading physicians and Governmental officials regarding the inherent risks of Baycol) would ineluctably result in false Medicare and Medicaid claims being submitted and paid.

270. The Government has been substantially damaged as a result of Bayer's improper conduct because the Government paid money to Bayer for a drug that it would not have purchased had it known the full truth. In essence, Bayer increased its market share and profits by improperly paying kickbacks to induce doctors to prescribe Baycol. Bayer also misreported and withheld material information relating to the safety of the drug, thereby inappropriately increasing its market share as well. As a result, the Government and ultimately the American public were damaged by Bayer's conduct.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION

False Claims Act: Presentation of False Claims
31 U.S.C. § 3729(a)(1)

271. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the Defendants have knowingly presented or caused to be presented to

officers or employees of the United States Government false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1).

SECOND CAUSE OF ACTION

False Claims Act: Making or Using False
Record or Statement to Cause Claim to be Paid
31 U.S.C. § 3729(a)(2)

272. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein the Defendants have knowingly made, used, or caused to be made or used false records or statements – *i.e.*, the false certifications and representations made or caused to be made by the Defendants, to get false or fraudulent claims paid or approved by the Government in violation of 31 U.S.C. § 3729(a)(2).

273. Defendants have knowingly caused physicians and other healthcare providers to submit bills to the United States Government and to Medicaid as a result of the payment of the above-described kickbacks.

274. The payment of kickbacks to induce prescriptions constitutes remuneration to increase the level of business in violation of the anti-kickback statute.

275. As a result of the conduct set forth in this cause of action, the Government suffered harm as a result of paying or reimbursing for pharmaceuticals which, had the Government known such pharmaceuticals were prescribed as a result of kickbacks, the Government would not otherwise have paid for and/or reimbursed.

THIRD CAUSE OF ACTION

California False Claims Act
Cal. Govt. Code § 12651(a)

276. This is a claim for treble damages and penalties under the California False Claims Act, Cal. Govt. Code §§ 12651(a)(1) and (2).

277. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

278. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

279. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants illegal off-label marketing practices and illegal inducements.

280. By reason of the Defendants' acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

281. The State of California is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

FOURTH CAUSE OF ACTION

Delaware False Claims And Reporting Act
6 Del C. § 1201(a)

282. This is a claim for treble damages and penalties under the Delaware False Claims and Reporting Act, 6 Del. C. §§ 1201(a)(1) and (2).

283. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

284. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

285. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants illegal off-label marketing practices and illegal inducements.

286. By reason of the Defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

287. The State of Delaware is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

FIFTH CAUSE OF ACTION

Florida False Claims Act
Fla. Stat. Ann. § 68.082(2)

288. This is a claim for treble damages and penalties under the Florida False Claims Act, Fla. Stat. Ann. § 68.082(2).

289. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

290. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

291. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants illegal off-label marketing practices and illegal inducements.

292. By reason of the Defendants' acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

293. The State of Florida is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

SIXTH CAUSE OF ACTION

Hawaii False Claims Act
Haw. Rev. Stat. § 661-21(a)

294. This is a claim for treble damages and penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a).

295. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

296. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants illegal off-label marketing practices and illegal inducements.

297. By reason of the Defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

298. The State of Hawaii is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

SEVENTH CAUSE OF ACTION

Illinois Whistleblower Reward And Protection Act
740 Ill. Comp. Stat. § 175/3(a)

299. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward And Protection Act, 740 Ill. Comp. Stat. § 175/3(a).

300. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

301. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

302. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants illegal off-label marketing practices and illegal inducements.

303. By reason of the Defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

304. The State of Illinois is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

EIGHTH CAUSE OF ACTION

Louisiana False Claims Act/Medical Assistance Programs Integrity Law
46. La. Rev. Stat.c. 3 § 438

305. This is a claim for treble damages and penalties under the Louisiana False Claims Act, 46. La. Rev. Stat.c. 3 § 438.

306. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

307. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Louisiana State Government to approve and pay such false and fraudulent

claims. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants illegal off-label marketing practices and illegal inducements.

308. By reason of the Defendants' acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

309. The State of Louisiana is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

NINTH CAUSE OF ACTION

Massachusetts False Claims Law
Mass. Gen. Laws ch. 12 § 5B

310. This is a claim for treble damages and penalties under the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §§ 5B(1), (2).

311. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts Commonwealth Government for payment or approval.

312. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts Commonwealth Government to approve and pay such false and fraudulent claims.

313. The Massachusetts Commonwealth Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or

presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants illegal off-label marketing practices and illegal inducements.

314. By reason of the Defendants' acts, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

315. The Commonwealth of Massachusetts is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TENTH CAUSE OF ACTION

Nevada False Claims Act
Nev. Rev. Stat. Ann. § 357.040(1)

316. This is a claim for treble damages and penalties under the Nevada False Claims Act, Nev. Rev. Stat. Ann. §§ 357.040(1)(a), (b).

317. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

318. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

319. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by

Defendants, paid and continues to pay the claims that would not be paid but for Defendants illegal off-label marketing practices and illegal inducements.

320. By reason of the Defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

321. The State of Nevada is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

ELEVENTH CAUSE OF ACTION

Tennessee Medicaid False Claims Act
Tenn. Code Ann. § 71-5-182(a)(1)

322. This is a claim for treble damages and penalties under the Tennessee Medicaid False Claims Law, Tenn. Code Ann. §§ 71-5-182(a)(1).

323. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

324. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

325. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants illegal off-label marketing practices and illegal inducements.

326. By reason of the Defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

327. The State of Tennessee is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TWELFTH CAUSE OF ACTION

Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. § 36.002

328. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. § 36.002.

329. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

330. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

331. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants illegal off-label marketing practices and illegal inducements.

332. By reason of the Defendants' acts, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

333. The State of Texas is entitled to two times the amount of actual damages plus the maximum penalty of $15,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

THIRTEENTH CAUSE OF ACTION

District of Columbia False Claims Act
D.C. Code Ann. § 2-308.03 *et seq.* (formerly § 1-1188.14, *et seq.*)

334. This is a claim for treble damages and penalties under the District of Columbia False Claims Act, D.C. Code Ann. § 2-308.14.

335. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

336. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants illegal off-label marketing practices and illegal inducements.

337. By reason of the Defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

338. The District of Columbia is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent

claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

FOURTEENTH CAUSE OF ACTION

New York False Claims Act
N.Y. Finance Law § 187, et seq.

339. This is a claim for treble damages and penalties under the New York False Claims Act.

340. By virtue of the acts described above, Defendants "knowingly present[ed], or cause[d] to be presented, to any employee, officer or agent of the state or a local government, a false or fraudulent claim for payment or approval," in violation of N.Y. Fin. Law § 189(1)(a).

341. By virtue of the acts described above, Defendants "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or a local government," in violation of N.Y. Fin. Law § 189(1)(b).

342. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made by the Defendants, paid and continues to pay the claims that would not be paid but for the acts or conduct of Defendants.

343. By reason of the Defendants' acts, the State of New York has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

344. Pursuant to N.Y. Fin. Law § 189(1)(g), the State of New York is entitled to three times the amount of actual damages plus the maximum penalty of $12,000 for

each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

WHEREFORE, Relator, on behalf of the United States Government and the State Plaintiffs, demands judgment against the above-named Defendants, ordering that:

a. Defendants pay an amount equal to three times the amount of damages the United States Government has sustained because of Defendants' actions which Relator currently estimates to be in the hundreds of millions of dollars, plus a civil penalty of not less than $5,500 and not more than $11,000 or such other penalty as the law may permit and/or require for each violation of 31 U.S.C. § 3729, *et seq.*;

b. Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) of the False Claims Act and/or any other applicable provision of law;

c. Relator be awarded all costs and expenses of this action, including attorneys' fees and costs as provided by 31 U.S.C. § 3730(o) and any other applicable provision of the law;

d. Relator and the named State Plaintiffs be awarded an amount equal to three times the amount of damages that California, Delaware, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Nevada, Tennessee, Texas and the District of Columbia have sustained, respectively, as a result of Defendants' actions, as well as a civil penalty against the Defendants of a statutory maximum for each violation of each state's FCA: Cal. Govt. Code § 12651; 6 Del. C. § 1201; Fla. Stat. Ann. § 68.082; Haw. Rev. Stat. § 661-21; 740 Ill. Comp. Stat. § 175/3; 46 La. Rev. Stat. c. 3, sec. 437.1 *et seq.*; Mass. Gen. Laws Ch. 12 § 5B.; Nev. Rev. Stat. Ann. § 357.040; Tenn. Code Ann. § 71-5-182; Tex.

Hum. Res. Code Ann. § 36.110; D.C. Code Ann. § 2-308.14; and N.Y. Fin. Law § 189(1)(g);

e. Relator and the Plaintiff State of Texas be awarded an amount equal to two times the amount of damages that Texas has sustained as a result of the Defendants' actions, as well as civil penalty against the Defendants of a statutory maximum for each violation of Tex. Hum. Res. Code Ann. § 36.002;

f. Relator be awarded the maximum amount allowed pursuant to Cal. Govt. Code § 12652(g); 6 Del. C. § 1205; Fla. Stat. Ann. § 68.085; Haw. Rev. Stat. § 661-27; 740 Ill. Comp. Stat. § 175/4(d); 46 La. Rev. Stat. c. 3, sec. 437.1 *et seq*; Mass. Gen. Laws Ch. 12 § 5F.; Nev. Rev. Stat. Ann. § 357.210; Tenn. Code Ann. § 71-5-183(c); Tex. Hum. Res. Code Ann. § 36.110; D.C. Code Ann. § 2-308.15(f); and N.Y. Fin. Law § 190(6);

g. Relator be awarded all costs and expenses associated with the pendent State claims, including attorney's fees; and,

h. Relator and State Plaintiffs be awarded such other and further relief as the Court may deem to be just and proper.

TRIAL BY JURY

Relator hereby demands a trial by jury as to all issues.

Dated: New York, New York
November 23, 2010

DIAMOND MCCARTHY LLP
Attorneys for Relator Laurie Simpson

By:
/s/ Robert W. Sadowski
Robert W. Sadowski (RS-4473)
Raphael Katz (RK-6603)
The New York Times Building
620 8th Avenue, 39th Floor
New York, New York 10018
Telephone: (212) 430-5407
Facsimile: (212) 430-5417
rsadowski@diamondmccarthy.com

BOIES, SCHILLER & FLEXNER LLP
Attorneys for Relator Laurie Simpson

By:
/s/ Edward Normand
Edward Normand
333 Main Street
Armonk, NY 10504
Telephone: (914) 749-9200

CERTIFICATE OF SERVICE

I, Robert Sadowski, hereby certify that on this 23rd day of November, 2010, true and correct copies of the foregoing proposed Second Amended Complaint were electronically filed and served on all attorneys of record and liaison counsel.

/s/ Robert W. Sadowski
Robert W. Sadowski